

**EXPERT REPORT OF JONATHAN E. GREENLEAF, M.D. REGARDING  
INVALIDITY OF THE KFX PATENTS**

Pursuant to the provisions of Rule 26(a)(2) of the Federal Rules of Civil Procedure, I, Jonathan E. Greenleaf, M.D., an expert witness for Defendant Arthrex, Inc. (“Arthrex”), hereby set forth my expert report as follows.

**I. QUALIFICATIONS AND PUBLICATIONS**

My name is Jonathan Greenleaf and I have been a practicing orthopedic surgeon for more than 22 years. I am certified by the American Board of Orthopedic Surgery and my area of specialty is sports medicine and more specifically arthroscopic surgery of the shoulder and knee. I graduated from Wesleyan University in Middletown, Connecticut with a B.A. in Biology in 1981. I attended the Boston University School of Medicine and received my M.D. in 1985. I interned at the Eastern Virginia Medical Center, in Norfolk, Virginia, from June 1985 – June 1986. I conducted my residency, combined with my residency in orthopedic surgery, at the Boston University School of Medicine from June 1986 – June 1990. I was name chief resident in 1989. I was a orthopedic fellow at the Eastwood Orthopaedic Clinic, at the Orthopaedic Healthcare Northwest, PC in Eugene, Oregon and at Aukland University, New Zealand.

In addition to my private practice, I currently serve as the Director of Sports Medicine at Nike, Inc. in Beaverton, Oregon. As the Director of Sport Medicine, I provide medical attention to several Nike-sponsored professional athletes and assist Nike employees with designing sports equipment, including bracing, protective gear, and specialty gear for NBA players. I am also the team physician for the Portland Timbers professional soccer team. As such, I provide medical attention to the players on the team. In the past, I was the team physician for the Portland Trailblazers professional basketball team and provided medical attention to the players on that team as well.

I have two teaching appointments at Oregon Health and Science University (OHSU). I am a master instructor for the Arthroscopy Association of North America (AANA) and I have also instructed for the American Orthopedic Society for Sports Medicine (AOSSM).

During my 22 years of practicing, I have used and have become very familiar with many different types of suture anchors, including anchors that are screwed into the bone, anchors that are pounded into the bone, anchors that capture suture without the need for tying a knot, and anchors that require knots to be tied in order to secure the suture to the anchor or to tissue. I have also used two-piece suture anchors that capture suture in between the two portions of the anchor. I describe each of these different types of anchors below.

I am also very familiar with the use of the accused anchors in this case; PushLock anchors, SwiveLock anchors, Corkscrew anchors and Bio-Tenodesis anchors. I am very familiar with the accused SutureBridge and SpeedBridge methods. I am also familiar with other suture bridging techniques used in the rotator cuff in which suture is “bridged” from one anchor to another anchor in order to re-approximate the tissue footprint. These different surgical methods and anchors are described in detail below.

A further description of my qualifications, and a list of my publications, are set forth in my CV, which is attached to this report as Ex. 1.

## **II. DATA AND INFORMATION CONSIDERED**

My conclusions and opinions as set forth below are based on the data and information described below, on my review and analysis of the materials in Ex. 2, my participation in testing conducted in this case, as well as my knowledge and experience with suture anchors and surgical procedures from my 22 years of practice in the field of orthopedic and arthroscopic surgery and research.

### **III. EXPERT TESTIMONY DURING PAST FOUR YEARS**

Over the past four years, I have provided expert testimony in the following cases:

- 1) *Grossnickle v. A. Brooke Benz, M.D., et al.*, Multnomah County Circuit Court, Case No: 0703-02834. Trial testimony in April 2009.
- 2) *Brooke Benz, M.D., et al. v. Stryker*, Multnomah County Circuit Court, Case No: 0703-02834. Trial testimony in March 2009
- 3) *Goedecke v. Orthopedic and Fracture Clinic, P.C.*, Multnomah County Circuit Court, Case No: 0709-10565. Trial testimony in January 2010.
- 4) *Matthew Beale v. I-Flow Corporation*, Multnomah County Circuit Court, Case No: 0801-01554. Trial testimony in January 2010.
- 5) *Smith & Nephew, Inc., et al. v. Arthrex, Inc.*, United States District Court for the District of Oregon, Case No: 04-CV-0029. Deposition testimony (April 2011) and trial testimony (June 2011).

### **IV. COMPENSATION**

I am being compensated for my time spent working on this case at the following rates:

- i) review of records and preparation of expert report: \$600 per hour;
- ii) deposition testimony: \$750 per hour; and
- iii) trial testimony: \$1000 per hour/\$8000 per day.

### **V. SUMMARY OF MY OPINIONS**

Based upon my experience, my review and consideration of the materials identified below, the materials identified in Ex. 2, and my participation in, and observation of, testing conducted in this case, it is my opinion that each limitation of the asserted claims of U.S. Patent Nos. 7,585,311 ("the '311 Patent") (Ex. 3); claims 1-7 and 11-19 of U.S. Patent No. 8,100,942

(“the ‘942 Patent”) (Ex. 4); and claims 1-7 and 14-17 of U.S. Patent No. 8,109,969 (“the ‘969 Patent”) (Ex. 5) (the ‘311, ‘942 and ‘969 Patents, collectively, “the KFx Patents”) is disclosed in, and anticipated by, the work performed by Arthrex and Dr. Neal ElAttrache during 2003 and 2004 (“the ElAttrache/Arthrex Work”).

It is also my opinion that a person of ordinary skill in the art of orthopedic surgery, during 2004, would have thought it was obvious to modify the ElAttrache/Arthrex Work and/or to combine at least two of the ElAttrache/Arthrex Work, the Millett Work, the Thal ‘168 Patent, the Burkhardt ‘272 Patent, the ElAttrache ‘281 Patent, the Bio-Tenodesis Screw, the Guanche Work, the Greenfield ‘835 Patent, the Thal ‘904 Publication and others and arrive at the limitations of each of the asserted claims of the KFx Patents. Thus, the asserted patent claims are invalid for these reasons as well.

I further understand that during prosecution of the KFx’ Patents, the examiner stated he was allowing the claims over the applied prior art references because those references did not disclose after inserting the second anchor, tensioning the suture to compress an area of tissue to bone between the edge of the soft tissue and the first anchor. It is my opinion that each of the ElAttrache/Arthrex Work, the Millett Work (and the Millett Article) and the Greenfield ‘835 Patent teach a person of ordinary skill in the art that the suture is tensioned after the anchor is already inserted into the bone.<sup>1</sup> Thus, each of these references teach the same limitation the Examiner believed to be missing from the applied references. It is my opinion that had the Examiner known that fact, he would not have allowed the claims of the KFx Patents.

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<sup>1</sup> I disagree that the suture eyelet portion at the end of the Bio-Tenodesis inserter, as used in the Arthrex/ElAttrache Work, is part of the anchor. But I understand from reviewing KFx’s infringement contentions that it is KFx’s position in this case that Arthrex’s Bio-Tenodesis Screw is an infringing product which means that KFx must consider the suture eyelet portion at the end of the Bio-Tenodesis driver to be part of the anchor.

It is further my opinion that claim 24 of the '311 Patent, claims 16 and 19 of the '942 Patent and each asserted claim of the '969 Patent are invalid because, to the extent they are being asserted against Arthrex's accused lateral anchors, they are not supported by a sufficient written description that would enable a person of ordinary skill in the art to make and use the invention and also because the inventors did not describe their best mode.

## VI. THE KFX PATENTS AND PROSECUTION HISTORIES

I have reviewed KFx's infringement contentions and interrogatory answers and understand that KFx is asserting claims 1, 5-7, 11-12, 14-21, 23-25, and 28-30 of the '311 Patent against Arthrex. I also understand that KFx is asserting claims 1-7 and 9-19 of the '942 Patent and claims 1-7 and 13-17 of the '969 Patent against Arthrex.

I also understand from reviewing KFx's infringement contentions that it is KFx's position the claims of the '311 and '942 Patents are entitled to a priority date of September 17, 2004 (Ex. 6 at 4; Ex. 7 at 5) and that the claims of the '969 Patent are entitled to a priority date of June 1, 2005. Ex. 7 at 5. I understand that in order to qualify as prior art, a reference must have a date prior to those respective priority dates.<sup>2</sup>

The KFx patents cover a surgical method of attaching soft tissue to bone. Claim 1 of the '311 Patent, for example,<sup>3</sup> covers a method of inserting a first suture anchor into bone through soft tissue and into the bone underneath the soft tissue. The suture attached to the first anchor is passed from the first anchor over the soft tissue. A second anchor is then inserted into the bone

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<sup>2</sup> I understand from reviewing KFx's Supplemental Response to Interrogatory No. 4 that KFx states that the subject matter claimed in the '311 Patent was conceived on or around January 23, 2004. Ex. 8 at 7-8. I am not aware of any documents or other corroborative evidence to support this claim by KFx. At best, the materials I have seen could support a conception date of September 8, 2004 for the '311 Patent claims. Ex. 43 at KFX 2136-42; Ex. 42.

<sup>3</sup> Although I generally describe claim 1 of each of the KFx Patents, each asserted claim is reproduced in its entirety in the appended claim charts.

by screwing it into the bone adjacent to the soft tissue so that it is not underneath the soft tissue. The claim then requires that after the second anchor is inserted into bone, the suture attached to the first anchor is then tensioned to compress an area of tissue to bone between the edge of the soft tissue and the first anchor. Lastly, after the second anchor is inserted into bone, the claims require that the suture be fixedly secured to the second anchor without tying any knots.

Claim 1 of the '942 Patent is similar to claim 1 of the '311 Patent except that rather than requiring the insertion of the second anchor, the '942 Patent requires insertion of a distal member of a second anchor into bone where the second anchor is made up of the distal member and a proximal member. After the distal member is inserted into the bone, claim 1 of the '942 Patent requires that the suture attached to the first anchor be tensioned to compress an area of tissue to bone between the edge of the soft tissue and the first anchor. Lastly, after the suture is tensioned, the proximal member is moved toward the distal member in order to fixedly secure the suture at the second anchor position without tying any knots.

Claim 1 of the '969 Patent is also somewhat similar to claim 1 of the '942 Patent except that instead of inserting a distal member of a second anchor into bone, claim 1 of the '969 Patent requires inserting at least a portion of a second anchor into bone. After the at least a portion of the second anchor is inserted into bone, claim 1 requires that the suture attached to the first anchor be tensioned to compress an area of tissue to bone between the edge of the soft tissue and the first anchor. After the suture is tensioned, the suture is fixedly secured at the second anchor position without tying any knots. Claim 1 of the '969 Patent then requires at least one of the anchors to have certain structural features; an anchor tip and a hollow cylinder, where the anchor tip has an aperture through which suture is threaded prior to inserting the anchor.

The fact that the claims of the KFx Patents require the second anchor to be inserted before the suture is tensioned and before the suture is fixedly secured to the second anchor makes sense when considering the type of anchor described. The KFx Patents describe a two-piece anchor having an anchor base 100 and an anchor top 200. The anchor base is first screwed into the bone so that it is securely fixed in the bone. The suture attached to the first anchor is then tensioned to compress the tissue back to the bone. Then after the surgeon is satisfied with the suture tension, the suture is fixedly secured to the second anchor by ratcheting down the anchor top onto the anchor base and locking the suture between the two anchor portions. This is described in the '311 Patent at column 7, lines 40-55 and column 13, lines 3-12. The two-piece anchor is shown below at Figs. 1 and 2.

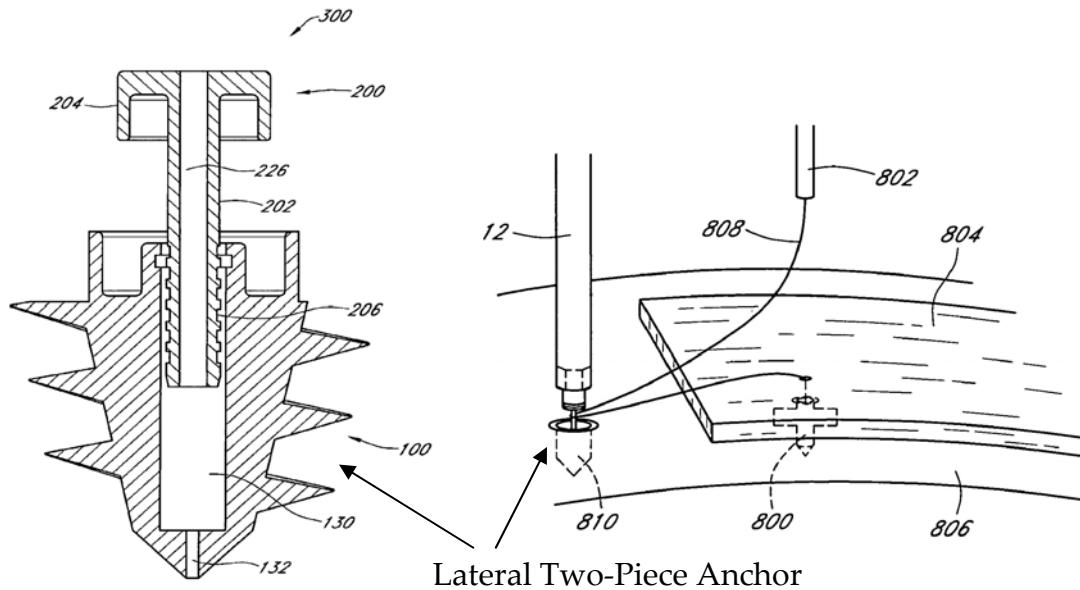


Fig. 1

Fig. 2

The '311 Patent describes that when the anchor top 200 is ratcheted all the way down into the central bore of the anchor base, passageways 302 and 304 are formed between the two anchor portions. These passageways 302, 304 are where the suture is captured and compressed so that it is securely attached to the anchor. '311 Patent at Column 7, lines 56-65 and column 13,

lines 3-12. The passageways 302, 304 formed when the anchor top 200 is ratcheted all the way into the anchor base 100, are shown below in Fig. 3. And the suture wedged between the two anchor portions is shown below in Fig. 4.

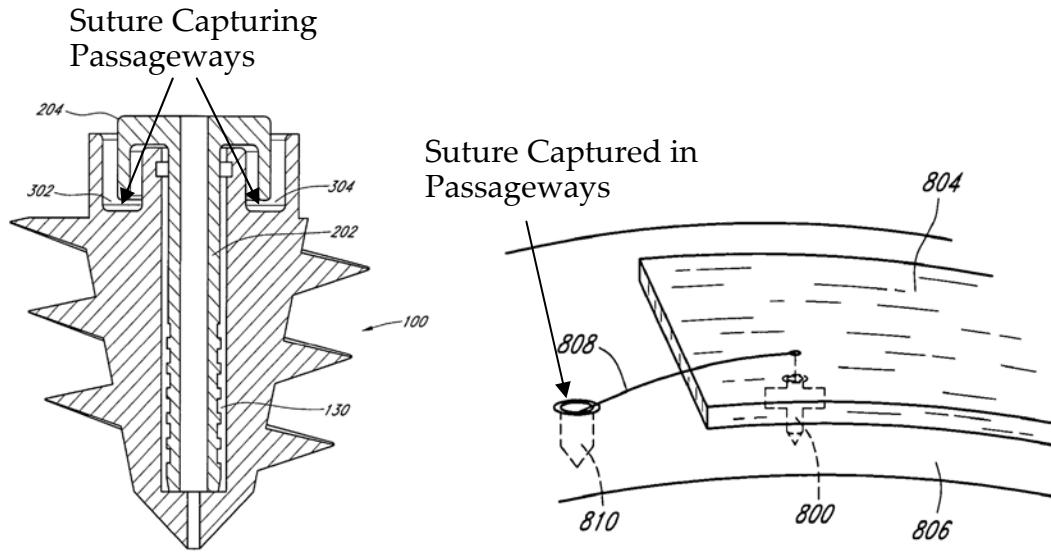


Fig. 3

Fig. 4

I also reviewed the prosecution histories of the KFx Patents and understand that for all three patents, the Examiner gave essentially the same reasons for allowing the claims over the prior art references applied in rejecting the claims. For example, in allowing the '311 Patent, the Examiner stated that neither U.S. Patent No. 5,891,168 to Thal ("the Thal '168 Patent"), nor U.S. Patent No. 5,634,926 to Jobe ("the Jobe '926 Patent") disclosed "after inserting the second anchor, tensioning the first length of suture to compress an area of tissue to bone between the edge of the soft tissue and the first anchor." Ex. 9 at KFX 1992-93. The same Examiner gave essentially the same reasons for allowing the claims for both the '942 and '969 Patents. Ex. 10 at KFX 32710; Ex. 11 at KFX 33036.

## VII. THE PRIOR ART

Although I describe specific prior art references in this section of my report, additional prior art references I rely upon for my opinions are identified and described in the claim charts appended to my report as Appendixes 1-13.

A. ElAttrache/Arthrex Work

I understand from discussions with Dr. Neal ElAttrache and a review of his deposition and other materials in this case, that he conceived of the idea to bridge suture between a medial anchor and a lateral anchor in the rotator cuff sometime during early 2003. His idea was to use an Arthrex corkscrew anchor medially (under the soft tissue) and a knotless Bio-Tenodesis Screw laterally (adjacent to the soft tissue). I also understand that he visited Arthrex during early 2003 to discuss his ideas with Arthrex employees. Those meeting are reflected in documents dated March 24-25, 2003, describing the use of 5.5mm Bio-Tenodesis screws in a rotator cuff repair. Ex. 12. By July 2003, Arthrex had constructed models of Dr. ElAttrache's concept. Exemplary images of those models are shown below in Figs. 5-7.

The first models constructed had a corkscrew anchor inserted medially into a sawbone and a Bio-Tenodesis Screw inserted laterally. Exs. 13-14. The suture attached to the corkscrew anchor was passed over the replicated soft tissue and secured between the second anchor and the bone without tying a knot. The Bio-Tenodesis Screw is a hollow screw positioned on a driver. The driver is also hollow. A FiberWire suture strand was passed through the hollow center of the driver so that a loop was formed at the bottom of the driver. The suture attached to the corkscrew anchor was threaded through the suture loop at the end of the driver. The suture loop was then advanced into the bone hole so that the suture loop, and the suture threaded through the loop, were positioned at the bottom of the bone hole. This is evident in Fig. 6 (below) since the

tip of the screw is at the top of the bone hole, which means the tip of the driver (and the suture loop) are at the bottom of the bone hole.

The suture from the corkscrew anchor was then tensioned to compress the simulated soft tissue to the sawbone. Once the tension was sufficient, the Bio-Tenodesis screw was then inserted (screwed) into the pre-formed hole thereby securing the suture to the screw by wedging the suture between the screw and the sawbone wall. No knots were tied to secure the suture to the second anchor. The finished model of this construct demonstrated that it was suitable for its intended purpose of securing tissue to bone. I reviewed the meta data associated with these images (Ex. 13) and understand the model was created by Mike Cottle, an Arthrex product manager at the time, on July 23, 2003. I also confirmed that the above information is correct in a conversation with Mike Cottle.



Fig. 5

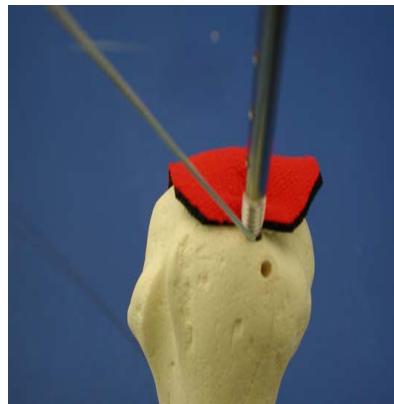


Fig. 6



Fig. 7

Mr. Cottle constructed another model of Dr. ElAttrache's concept on August 18, 2003. This information is confirmed by both Mr. Cottle and the meta data. Ex. 15. Images of the second model are shown below in Figs. 8-10.

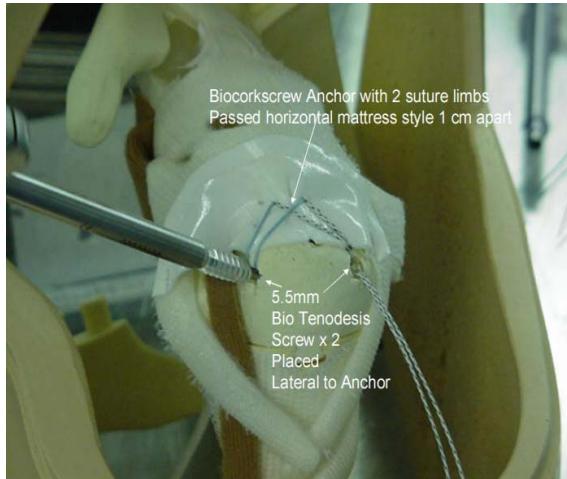


Fig. 8

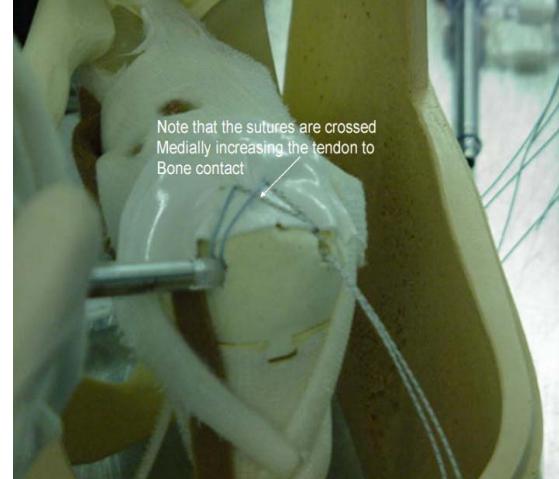


Fig. 9

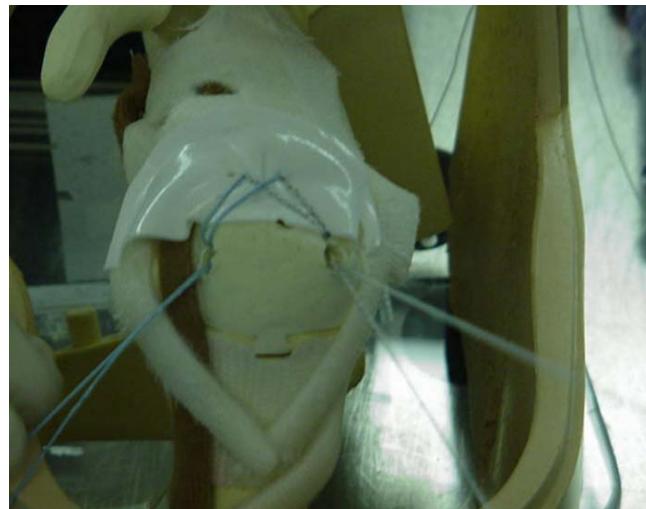


Fig. 10

In the model shown in Figs. 8-10, a corkscrew anchor is inserted medially and two Bio-Tenodesis screws are inserted laterally. Mr. Cottle confirmed that the method of inserting the first anchor, threading the suture from the first anchor through the suture loop of the Bio-Tenodesis screw, tensioning the suture while the suture loop is inside the bone hole, then inserting the second anchor to wedge the suture between the screw and the bone hole without

tying knots was the same for this model (Figs. 8-10) as it was for the model shown above at Figs. 5-7.

Arthrex constructed another set of double row models which were photographed on August 21, 2003. One model, shown in Fig. 11 below, included a single medial Corkscrew anchor and two lateral Bio-Tenodesis anchors. Ex. 16A. Another model, shown below in Fig. 12, included two medial Corkscrew anchors connected to two lateral Bio-Tenodesis anchors in a criss-cross fashion. Ex. 16B.

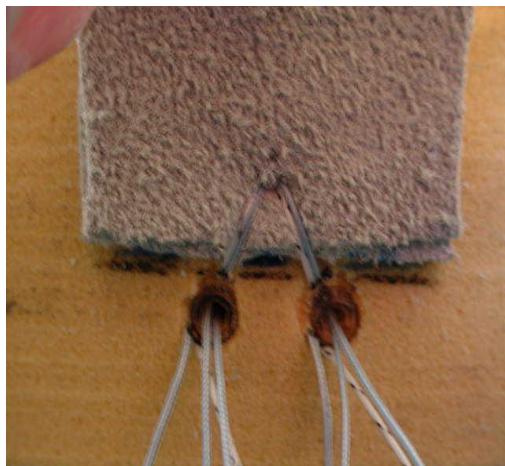


Fig. 11

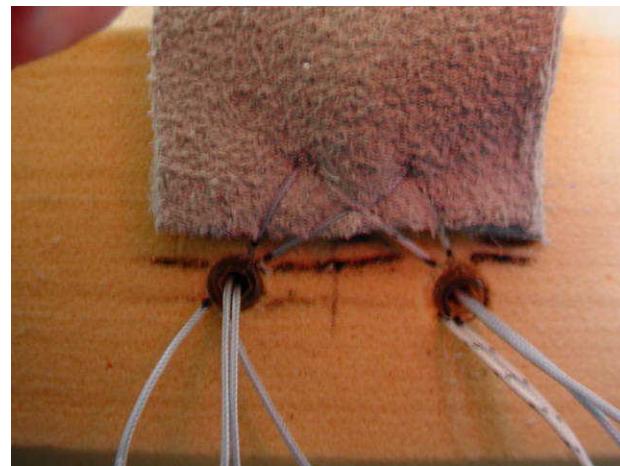


Fig. 12

The procedure for inserting the anchors is described in a draft surgical technique guide created by Mike Cottle on August 25, 2003. The technique guide describes that a FiberStick Snare is passed through the cannulation on the Bio-Tenodesis driver. Ex. 17. Then the FiberStick Snare is secured around the sutures coming from the medial anchor. Ex. 17. The tip of the inserter (with the loop of the FiberStick Snare) is positioned into the pilot hole and the suture from the medial anchor is tensioned. While tension is being maintained on the suture, the screw is inserted into the hole to wedge the suture between the anchor body and the bone wall. Ex. 17. The surgical technique describes this as a knotless repair. Ex. 17.

The surgical technique also includes results of peak load to failure testing conducted by Ashley Willobee at Arthrex, who conducted these tests on the models of Figs. 11-12 (above). The results of the testing show peak load to failure of 483N and 575N in 15lb. foam block. Ex. 17. The 15lb. foam block is intended to simulate average to good quality bone. I understand from speaking with both Ms. Willobee and Mr. Cottle that these results further demonstrated to both Ms. Willobee and Mr. Cottle that Dr. ElAttrache's constructs were suitable for their intended purpose of securing tissue back to bone.

I understand that since the construct was found to be suitable for its intended purpose (by building the July 2003 models, the August 2003 models and the August 2003 test), as of the date the models were built and/or the test results were recorded, the construct was "actually reduced to practice" by Arthrex and that this reduction to practice occurred five or so months prior to KFx's earliest claimed conception date of January 23, 2004 and more than a year before any evidence of KFx's alleged conception. I further understand that this means KFx's invention was made in the United States by another inventor long before KFx conceived of the idea, thus making the ElAttrache/Arthrex construct prior art to the KFx Patents.

I also reviewed a proposal dated November 19, 2003, submitted to Arthrex by Dr. David Kim, Dr. ElAttrache's fellow at the Kerlan Jobe Orthopedic Clinic ("KJOC"). Ex. 18. The proposal describes testing that KJOC intended to conduct and which it was seeking Arthrex to sponsor. The proposal describes "a modified double row construct consisting of a medial row of two 6.5mm metal corkscrew anchors with horizontal mattress sutures and incorporating these sutures with laterally placed 5.5mm Bio-Tenodesis screws placed in a knotless fashion to create a linkage between the two rows. Ex. 18. I understand from speaking with Dr. ElAttrache this proposal describes a double row construct in which the medial row contains two corkscrew

anchors and the lateral row contains two Bio-Tenodesis screws where one suture strand from each medial anchor is connected to each lateral anchor in a criss-cross pattern. Other configurations using four anchors (e.g., suture extending straight across from medial to lateral, without criss-crossing) were also considered by Dr. ElAttrache at that time.

I further understand that on January 21, 2004, Dr. ElAttrache performed a surgical procedure on a live patient using his double row technique with suture linking two of the rows. I have reviewed both a surgical report (Ex. 19) and a video (Ex. 20) of that procedure. According to the surgical report, the procedure was performed at the Kerlan Jobe Surgery Center in Los Angeles, California. Dr. ElAttrache was assisted by Dr. DeLamora. Ex. 19. Dr. ElAttrache inserted a 5.5mm Bio-Corkscrew anchor medially which had one strand of #2 FiberWire suture attached to it. Ex. 19, Ex. 20. The suture was brought through the supraspinatus tendon (a.k.a. rotator cuff). Ex. 19, Ex. 20. A 5.5mm Bio-Tenodesis screw was placed laterally. A punch was used to create the hole for the Bio-Tenodesis screw. Ex. 19, Ex. 20. Prior to placing the screw, the sutures from the medial anchor were threaded through the loop of the FiberWire suture at the end of the screwdriver (inserter). Ex. 19. Ex. 20. The end of the inserter, with the FiberWire loop, was placed at the bottom of the punch hole. Ex. 19. Ex. 20. Tension was then applied to the sutures coming from the medial anchor and through the FiberWire loop. Ex. 19. Ex. 20. As Dr. ElAttrache explained, the application of tension advanced the rotator cuff and reduced the tendon nicely onto its normal lateral attachment site. Ex. 19. Then the Bio-Tenodesis screw was inserted into the hole and tightened down. Ex. 19. Ex. 20.

Dr. ElAttrache also describes that he tied knots over the back of the screw, locking the repair into place. Ex. 19. I have spoken with him and I understand that Dr. ElAttrache believed that the construct would have been strong enough without the need for tying any knots because

he was aware of the prior testing conducted by Arthrex where very good load to failure values were received on the construct in sawbones representative of relatively strong bone. As Dr. ElAttrache explained, since this was the very first time his construct was being implemented into a live patient, and since this was a sixty-year-old woman with thin, soft, bone, he took a “belt and suspenders” approach and tied the knots. Ex. 21 at 100-101; 113-115. Dr. ElAttrache believed, however, that the suture was fixedly secured to the anchor (i.e., cannot be easily moved relative to the anchor) without any knots.

I further understand that Dr. ElAttrache’s January 21, 2004 surgery constitutes a prior public use of KFx’s alleged invention and this occurred two days prior to KFx’s earliest claimed conception date of January 23, 2004.

I understand from discussions with Dr. ElAttrache that in August 2004, soon after Dr. Maxwell Park joined KJOC as a fellow, Dr. Park and Dr. ElAttrache began working on the linked double row construct described in the November 2003 proposal to Arthrex in which two Bio-Tenodesis screws would be used on the lateral side in a 4-anchor criss-cross configuration. Work continued without interruption to build the constructs. Preparations were made, including identifying the number of cadaver shoulders required, the instrumentation to be used, the specific anchors to be used, among other details. On September 23, 2004, Dr. Park wrote to Arthrex and requested instrumentation for additional testing. Ex. 22. And on October 1, 2004, Drs. ElAttrache and Park photographed a construct in a cadaver shoulder in which two Corkscrew anchors were inserted medially and the sutures were passed through the rotator cuff. Ex. 23. One limb of suture from each medial anchor was then threaded through the suture eyelet at the end of first Bio-Tenodesis driver. The tip of the driver was placed at the bottom of a first lateral preformed bone hole. The sutures coming from the two medial anchors were then tensioned

bringing the cuff back to its original footprint. The screw was then inserted locking the two suture strands between the anchor body and the bone wall. This was repeated for the second lateral anchor. The construct Drs. ElAttrache and Park prepared is shown below at Fig. 13. I understand that the continued work on this matter from August through October 1, 2004 is prior art to the KFx patents.

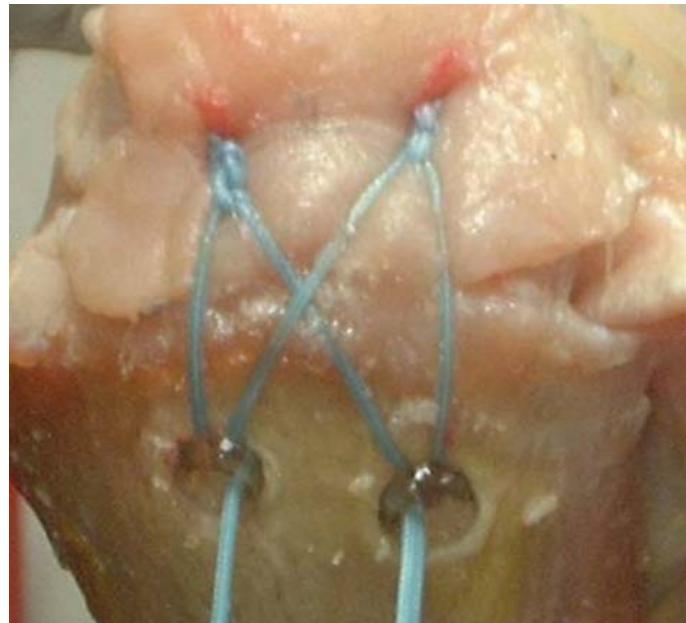


Fig. 13

B. The Millett Article (and Work)

The Millett Article, titled “Mattress Double Anchor Arthroscopic Rotator Cuff Repair” was published in October 2004 (Ex. 24), however, I understand from speaking with Dr. Millett that he conceived of the idea around March 2003 and had been performing his work since around that time. I also reviewed documents stating that KFx understands Dr. Millett was performing the work described in his article in the two years prior to its publication in October 2004. Ex. 25.

I further understand from Dr. Millett, and from reviewing documents, that Dr. Millett performed dozens of procedures using his technique between 2003 and 2004, including at least on April 25, 2003. Ex 26. I also know that prior to the publication of his article, Dr. Millett

publicly presented his construct to hundreds of orthopedic surgeons at Arthrex's Worldwide Surgeons Meeting ("WWSM"), in Naples, Florida, between January 8-10, 2004. I was a moderator at the WWSM and recall Dr. Millett's presentation. Dr. Millett also confirmed he presented his technique at the WWSM during my conversation with him. I also reviewed the materials publicly disclosed at the WWSM to confirm Dr. Millett did present his technique, including the presentation itself, the schedule of presentations, and an invoice showing that binders including the presentation materials were prepared for the attendees. Ex. 27.

I understand that the Millett Article is a printed publication and is dated October 2004 which makes it prior art to the '969 Patent because the '969 Patent has a priority date of June 1, 2005. I further understand that Dr. Millett's public presentation and materials available at Arthrex's WWSM constitutes prior art to the KFx Patents because as of January 10, 2003, it was described in a printed publication and the invention was publicly known by hundreds of other surgeons in the United States before KFX's earliest claimed conception date of January 23, 2004. I also understand that Dr. Millett's surgeries, in which he used his MDA technique, including the surgery on April 25, 2003, are prior art to the KFx Patents because they are public uses of the invention by another person in the United States and conceived and reduced to practice prior to KFx's earliest claimed conception date.

The Millett Article (and work) includes a four-anchor construct in which two anchors are placed medially and two anchors are placed laterally in a double row configuration. All four anchors are Corkscrew anchors. Ex. 24 at 878. The two rows of anchors are linked together by suture to form a criss-cross pattern. This pattern provides optimum compression of tissue back to the bone and is especially suitable for large tears where maximum compression is required to

recreate the original footprint. Dr. Millett's construct is shown below in Fig. 14 (Figure 6 of the Millett Article).

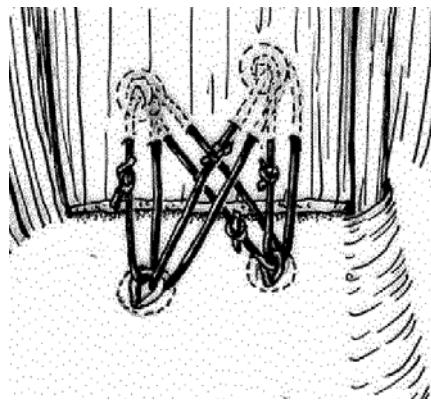


Fig. 14

The article/work includes a first anchor placed in the medial border of the footprint at the articular margin and the sutures are passed in a mattress configuration so that there are anterior and posterior limbs. The first anchor (like the other anchors) is a Corkscrew so it is screwed into the bone. The anchor has an eyelet on its top side and a suture is threaded through the eyelet. The placement of the first medial anchor is shown below in Fig. 15 (Figure 1 of the Millett Article).

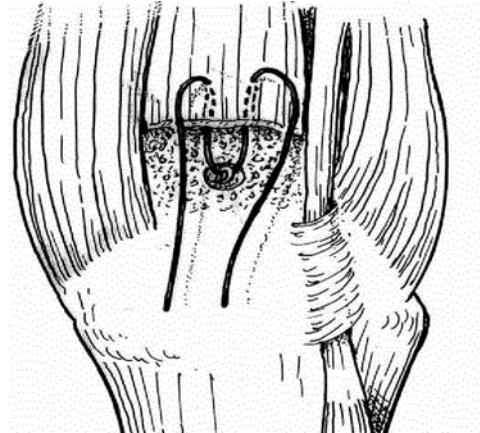


Fig. 15

The article/work includes a lateral anchor placed laterally on the tuberosity and that one limb from the medial suture is pulled through a loop of suture passed through the eyelet of the lateral anchor and then pulled through the eyelet of the lateral anchor. Those steps are shown below in Fig. 16 (Figure 3 of the Millett Article).

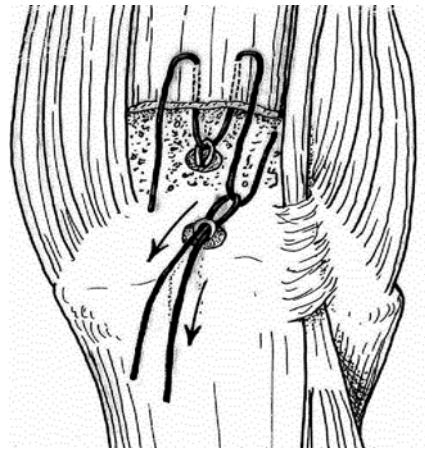


Fig. 16

As shown above, the second (lateral) is screwed into the bone (adjacent to the cuff) and then the suture from the medial anchor is passed through the eyelet of the second anchor. The suture linking the medial and lateral anchors is then secured using standard arthroscopic knot tying techniques and the tendon is compressed onto the tuberosity, thereby recreating the broad

footprint. A top view and a side view of the knot tying process is shown below in Fig. 17 (Figure 4 of the Millett Article).

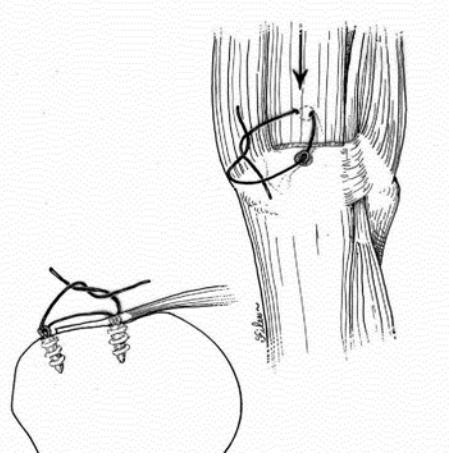


Fig. 17

Standard arthroscopic knot tying techniques, as described by Dr. Millett, require that the suture be tensioned as the knot is being tied. I know from my 22 years of experience with tying arthroscopic knots that in order to tie a knot in suture, the suture must be tensioned during the process. This is especially true when the suture is spanned across the top of tissue to compress the tissue back to the bone. In order to provide that compression, the suture must be tensioned during the knot tying process. During the knot tying process, the tension is applied to the suture as the surgeon forms the knots and then as the surgeon progresses the knot toward the tissue. Without tension being applied to the suture during the knot tying process, the tissue cannot be compressed to the bone in order to recreate the footprint.

### C. Thal '168 Patent

The Thal '168 Patent, titled "Process for Attaching Tissue to Bone Using a Captured-Loop Knotless Suture Anchor Assembly," was filed on October 1, 1997 and issued on April 6, 1999. Ex. 28. I understand the Thal '168 Patent is prior art to the KFx Patents because the invention was patented in the United States more than one year prior to any of the provisional

application filing dates of the KFx Patents. I also understand that the Thal '168 Patent is prior art to the KFx Patents because it was patented before KFx's earliest claimed conception date.

The basic construct of the Thal '168 Patent is shown below in Fig. 18. The Thal '168 Patent teaches inserting a first anchor 26 (with an attached loop of suture) into bone 28 (Ex. 28 at column 4, lines 34-36) then passing the attached suture loop through the tissue 30 creating a passage 44 in the tissue. Ex. 28 at column 4, lines 38-40. The suture loop is then captured by a second knotless anchor 24 and pressed into the bone 28. Ex. 28 at column 4, lines 45-47. As the suture loop is moved toward the bone hole and then pressed into the bone hole, the suture is tensioned and the tissue is compressed toward the bone.

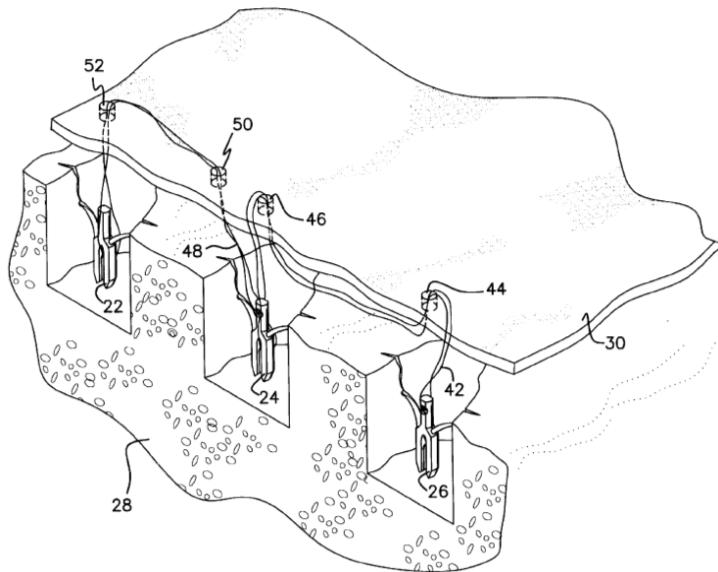


Fig. 18

#### D. The Greenfield '835 Patent

U.S. Patent No. 5,584,835 to Greenfield ("the Greenfield '835 Patent"), titled "Soft Tissue to Bone Fixation Device and Method" was filed September 8, 1994 and issued December 17, 1996. Ex. 29. I understand the Greenfield '835 Patent is prior art to the KFx Patents because

the invention was patented in the United States more than one year prior to any of the provisional application filing dates of the KFx Patents. I also understand that the Greenfield '835 Patent is prior art to the KFx Patents because it was patented before KFx's earliest claimed conception date.

The Greenfield '835 Patent describes a two-piece anchor having a base (bone anchor) 12 that screws into bone and a cap (suture anchor) 11 that gets inserted into the base to capture the suture by friction between the two anchor portions. Ex. 29 at column 6, line 66 – column 8, line 10. The cap engages with the inner portion of the base with multiple locking positions (very similar to the ratcheting engagement described in the '311 Patent). Ex. 29 at column 7, lines 55-65. After the base is screwed into bone (col. 7, lines 13-16), the suture is tensioned and then threaded through an aperture 22 in the cap 11. The cap is then fully engaged with the base which fixes the suture by friction between the two anchor portions. Ex. 29 at column 7, line 65-column 8, line 2; column 9, lines 40-44. The anchor base 12 and cap 11 are shown below in Fig. 19. And in Fig. 20 (also below), the cap is shown fully engaged with the base with suture captured between the two portions by friction.

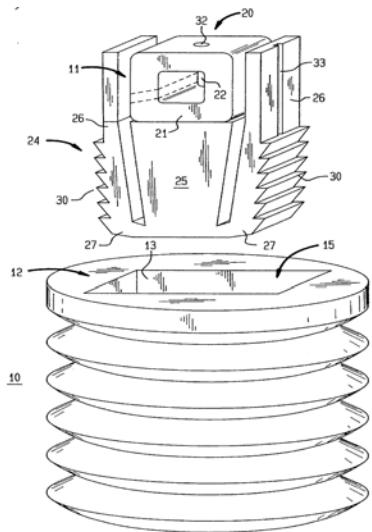


Fig. 19

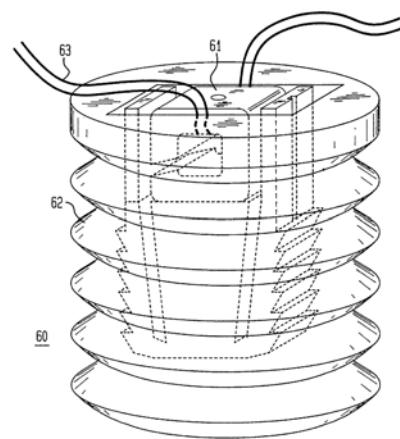


Fig. 20

The anchor disclosed in the Greenfield '835 Patent is functionally the same as the lateral anchor disclosed in the KFx Patents. Both have a base portion that screws into the bone. Both have a cap portion that ratchets down into the base portion. Both enable the surgeon to tension the suture after the base portion is inserted into bone. And both capture suture in between the two anchor portions by friction.

E. Thal '904 Publication

U.S. Patent Application Publication No. 2006/0079904 A1 to Thal ("the Thal '904 Publication"), titled "Multirow Knotless Suture Anchor Assembly," was filed on October 12, 2005 and issued on April 12, 2006. Ex. 30. The Thal '904 Publication claims priority to Provisional Application No. 60/617,640, filed on October 13, 2004 ("the '640 Provisional"). Ex. 31. I have also reviewed materials showing that Dr. Thal conceived of, and discussed with many DePuy Mitek personnel, the ideas described in the '640 Provisional and the '904 Publication at least as early as August 4, 2003. Ex. 32. I understand the Thal '904 Publication and/or Dr. Thal's work are prior art to the '969 Patent because it describes the invention in a printed publication before the claims of the '969 Patent were invented (June 1, 2005, according to KFx). I also understand that the '904 Publication is prior art to the KFx Patents because, among other reasons, the invention was publicly known by others in the United States before the claims of the KFx Patents were invented.

The Thal '904 Publication discloses a double row construct that includes a first (medial) anchor 14 screwed into bone underneath the soft tissue and in which the suture 16 attached to the first anchor is passed through the soft tissue so that it is on the top of the tissue. Ex. 30 at ¶ 30. A sleeve portion 127 of the second (lateral) anchor is then inserted into the bone adjacent to the soft tissue so that it is not underneath the soft tissue. Ex. 30 at ¶ 32. The suture 16 is then

captured by a forked tip of a plug portion 131 of the second anchor. Ex. 30 at ¶ 30. The suture is then tensioned as the plug is moved towards the lateral hole in which the sleeve is inserted. The tension on the suture compresses the tissue back to the bone. Compare Ex. 30 at Figs. 13 and 14. Finally, the plug portion 131 of the second anchor is inserted into the sleeve portion 127 of the second anchor and the suture 18 is captured by friction between both anchor portions similar to how the suture is captured in the lateral anchor of the KFx Patents. Ex. 30 at ¶ 32. These steps are also shown below in Figs. 21 and 22.

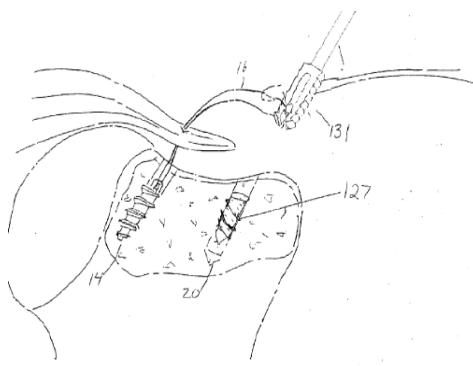


Fig. 21

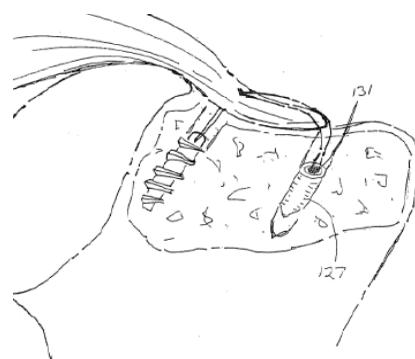


Fig. 22

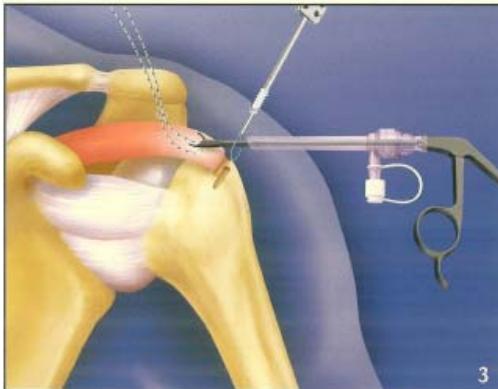
#### F. The Guanche Work

The Guanche Work is a rotator cuff repair procedure that I understand was conceived of and used by Dr. Carlos Guanche during 2003. I understand Dr. Guanche performed surgery on live patients using his procedure during 2003-2004, including at least on August 29, 2003. He also publicly described his technique at the Arthrex World Wide Surgeons Meeting held on January 8-10, 2004 in Naples, Florida (Ex. 33), as well as to various other surgeons (including Peter Millett) and Arthrex employees (including William Benavitz, Peter Dreyfuss, Mike Cottle, Ashley Holloway, Don Grafton and Jeff Wyman) between 2003 and March 2004. Ex. 33; Ex. 34.

I understand the Guanche Work is prior art to the KFx Patents because the invention was publicly used in surgery at least on August 29, 2003, which is more than one year prior to when

the invention is described in the September 17, 2004 Provisional Application. I also understand the Guanche Work is prior art to the KFx Patents because the invention was described in a printed publication, publicly known by others in the United States at the WWSM and conceived and reduced to practice before KFx's earliest claimed conception date.

As shown below in Figure 23, a strand of suture is passed through the medial portion of the rotator cuff in a mattress stitch and then passed over the top of the soft tissue. Both loose ends of the suture are then threaded through a suture eyelet at the end of the Bio-Tenodesis screw driver.



A 5.5 mm x 15 mm Bio-Tenodesis Screw is inserted onto the Bio-Tenodesis Driver and a #2 FiberWire suture loop is loaded through the driver cannulation. The loaded driver is inserted through the incision created for the pilot hole. The FiberWire loop is advanced into the subacromial space to create a large loop. A Suture Retriever is inserted through the lateral 5.75 mm cannula and the TigerWire suture tails are drawn through the FiberWire loop and out the lateral portal cannula.

Fig. 23

The suture eyelet of the Bio-Tenodesis is then positioned at the bottom of the bone hole laterally to the rotator cuff. The Bio-Tenodesis screw is then inserted into the bone hole to wedge the suture between the anchor body and the bone wall. This is shown below in Fig. 24.

Although this is a single anchor construct, because the two strands of suture span across the footprint of the tendon from medial to lateral and over the edge of the soft tissue, this construct provides many of the benefits of a linked double row construct.

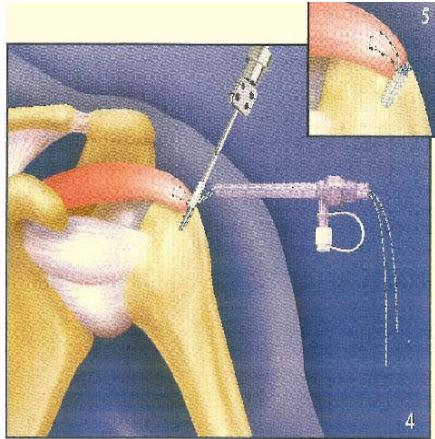


Fig. 24

G. The Burkhart '272 Patent

U.S. Patent No. 7,329,272 to Burkhart et al. ("the Burkhart '272 Patent") was filed on April 3, 2003 and issued on February 12, 2008. Ex. 35. I understand that the Burkhart '272 Patent is prior art to the KFx Patents because the invention is described in an application for patent filed by another in the United States before KFx's earliest claimed conception date.

The claims of the Burkhart '272 Patent cover aspects of one of the anchors that I understand KFx is accusing of infringing the KFx Patents; Arthrex's PushLock family of anchors used as the lateral anchor for the SutureBridge method. The Burkhart '272 Patent describes the eyelet at the end of the driver and the anchor body is spaced apart from the eyelet. The driver 100 with anchor body 20 and eyelet 50 are shown in Fig. 25 below.

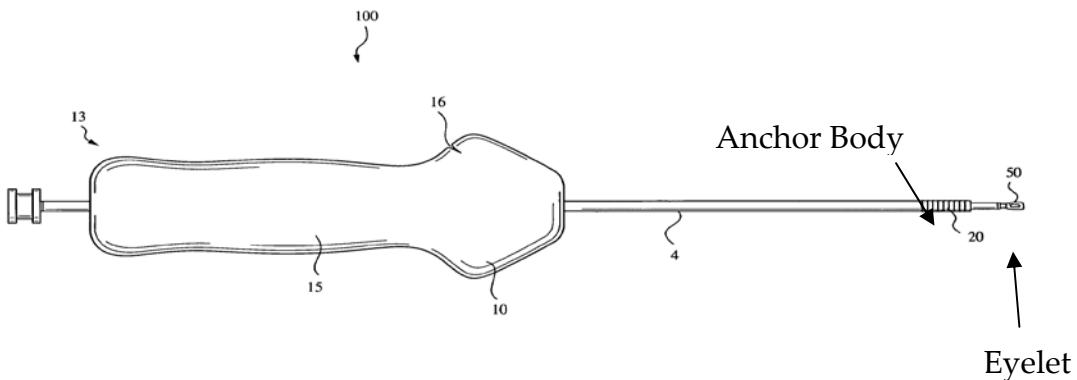


Fig. 25

Suture 80 (attached to soft tissue 70) is threaded through the eyelet 50 at the end of the inserter. In certain uses, the eyelet is then described as being placed at the bottom of the pre-formed bone hole 90 while the anchor body is just outside the hole. Tension is then applied to the suture 80 as it slides though the eyelet. Ex. 35 at column 4, lines 28-37. This is shown below in Fig. 26.

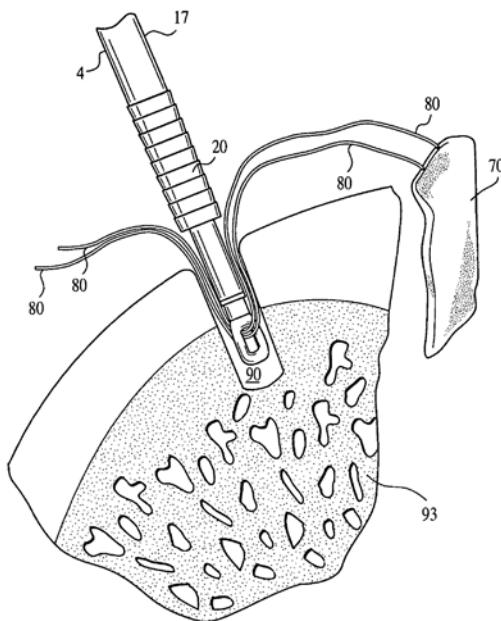


Fig. 26

Once tension is complete, the anchor body 20 is impacted into the bone hole 90 so that the suture is wedged between the anchor body and the bone hole on both sides of the anchor body. After the anchor body is inserted, the driver is removed. Ex. 35 at column 4, lines 37- 49. This is shown in Fig. 27 below.

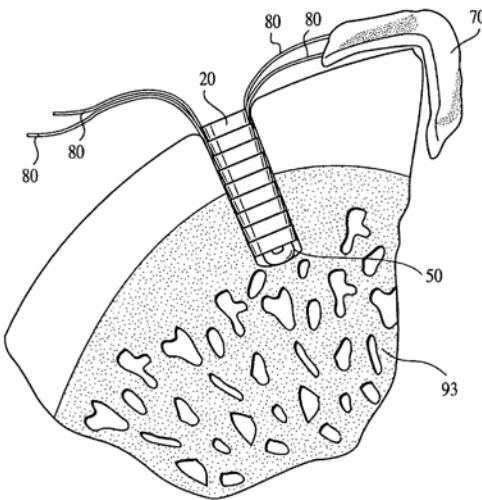


Fig. 27

#### H. The ElAttrache '281 Patent

U.S. Patent No. 6,544,281 to ElAttrache et al. ("the ElAttrache '281 Patent), titled "Graft Fixation Using a Screw or Plug Against Suture or Tissue" was filed June 22, 2001 and issued April 8, 2003. Ex. 36. I understand the ElAttrache '281 Patent is prior art to the KFx Patents because the invention is patented in the United States more than one year prior to the filing of any of KFx's provisional applications. I also understand the ElAttrache '281 Patent is prior art to the KFx Patents because the invention was patented before KFx's earliest claimed conception date.

The ElAttrache '281 Patent describes a knotless anchor similar to that described in the Burkhardt '272 Patent, except that the anchor is a screw instead of a plug and the eyelet is made of suture instead of plastic. Otherwise, the two devices described in both patents are functionally very similar. The ElAttrache '281 Patent describes aspects of Arthrex's Bio-Tenodesis screw, which is an anchor KFx accuses of infringing the KFx Patents and also the same anchor used in the ElAttrache/Arthrex prior art described above. Supra at 9-16. The driver 30 with suture eyelet 70 and separate screw anchor 10 are shown below in Fig. 28.

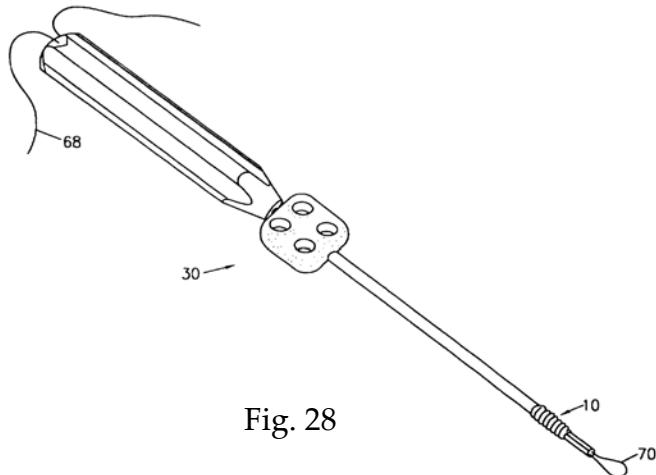


Fig. 28

Similar to the Burkhart '272 Patent and the PushLock family of anchors, the ElAttrache '281 Patent describes sutures 62 attached to soft tissue 60 being threaded through the suture eyelet 70 at the end of the driver 30. Ex. 36 at column 5, lines 13-21. This is shown below in Fig. 29.

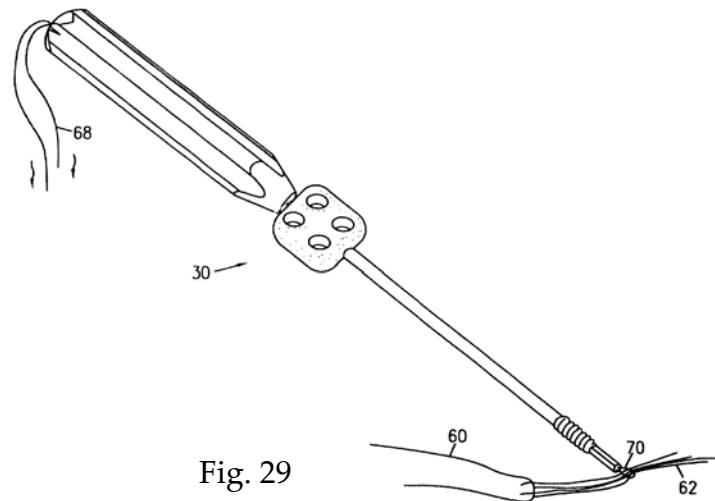


Fig. 29

In certain uses, the end of the driver is then placed into the bone hole 66, keeping the screw just outside the hole. Tension is then applied to the sutures 62 attached to the tissue 60

and the suture loop 70 is tightened. After adequate tension is applied the screw is inserted into the bone hole to wedge the suture 62 between the screw body and the bone hole on both sides of the anchor. This process is described at column 5, lines 22-47, and also shown below at Figs. 30 and 31.

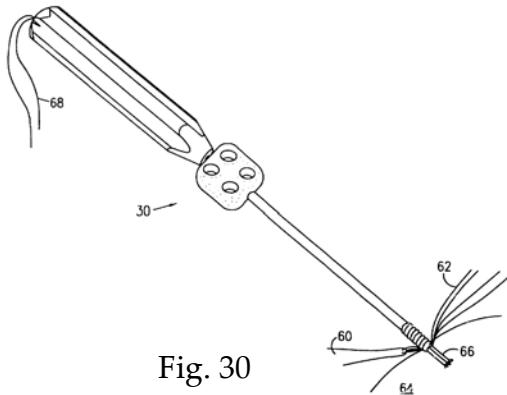


Fig. 30

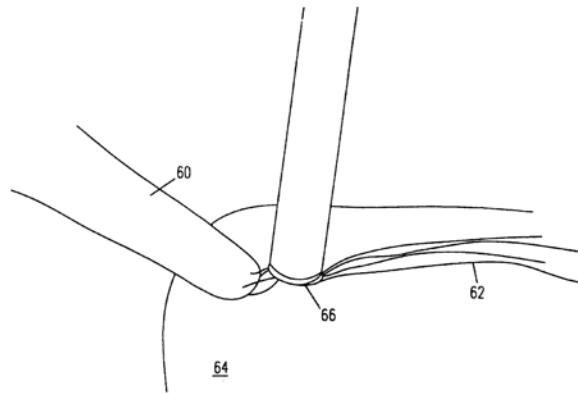


Fig. 31

## VIII. TESTING CONDUCTED

I participated in testing conducted by Dr. Robert Piziali at Exponent's laboratory in Menlo Park, California. The testing was conducted for two different prior art references; the ElAttrache/Arthrex work and the Millett work. Each test was conducted to determine whether there is a tension force applied to the suture being attached to the second anchor after the second anchor is already inserted into bone. I understand this was the limitation the Examiner believed was missing from the prior art references applied during prosecution of the KFx Patents. As shown below, the testing confirms my opinion that there is a tension force applied to the suture after the second anchor is inserted into the bone. The testing was conducted for two different anchors as the second anchor; the Bio-Tenodesis Screw (as used in the ElAttrache/Arthrex work) and the Corkscrew anchor (as in the Millett work).

### A. Testing Conducted on the ElAttrache/Arthrex Work

This testing was conducted to confirm whether a tension force is applied to the suture coming from the medial anchor after the tip of the driver of the lateral Bio-Tenodesis screw is placed into the bottom of the bone hole. I understand the Court interpreted the term “inserting [an anchor] into bone” to mean that the anchor is put or placed into the bone and does not need to be securely fixed in the bone. I also understand it is KFx’s position that the eyelet at the end of the driver of the accused PushLock and SwiveLock anchors is part of the anchor. I disagree with KFx’s position that the eyelet is part of the anchor.<sup>4</sup> However, for purposes of my opinions in my report and for this testing, I was asked to assume that KFx’s position is correct.

If KFx is correct and the eyelet at the end of the driver for PushLock and SwiveLock are part of the anchor, then it is my opinion that the eyelet at the end of the driver of the Bio-Tenodesis screw is also part of the anchor. Both eyelets (whether made of plastic or suture) serve the same purpose and are located in the same position relative to the anchor body on the driver. The purpose of both eyelets is to position the suture at the bottom of the bone hole until the anchor body is inserted into the hole to wedge the suture between the anchor body and the bone wall. And according to the Court’s claim construction advancing the eyelet to the bottom of the bone hole is the same as inserting an anchor into bone even though the eyelet is not securely fixed in the bone and can be easily removed.

The testing was performed using an Alex shoulder model. Instead of inserting a medial Corkscrew anchor, as described above for the ElAttrache/Arthrex Work, Dr. Piziali threaded a strand of FiberWire suture through a loop of suture tied to a load cell acting as the first anchor. I

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<sup>4</sup> I do not believe the eyelet at the end of the driver is part of the anchor. The eyelet serves a very different purpose than the anchor body. The eyelet’s sole purpose is to position the suture at the bottom of the hole so that the suture can be wedged between the anchor body and the bone wall. The eyelet does not anchor any portion of the suture to the bone. It is the anchor body that anchors the suture to the bone.

then passed both loose ends of the FiberWire suture through the simulated tissue and to the top of the tissue. I then drilled the hole for the lateral 5.5mm Bio-Tenodesis Screw using a 4.5mm drill bit. This is the same drill bit used by Mike Cottle in constructing his early model of the ElAttrache/Arthrex work, as described in Exs. 13-14.

I then inserted a strand of FiberWire suture through the cannula of the Bio-Tenodesis driver and captured the suture strand from the simulated medial anchor in the suture eyelet formed at the end of the driver. I then placed the tip of the driver and the suture eyelet (with sutures from the simulated medial anchor threaded therethrough) at the bottom of the bone hole. Then I tensioned the suture attached to the tensiometer representing the medial Corkscrew anchor. This compressed the simulated tissue back to the sawbone to reapproximate the original footprint of the tendon.

As I tensioned the suture, Dr. Piziali determined whether any measureable tension force was being applied to the suture. Dr. Piziali measured tension forces while I was tensioning the suture to compress the tissue back to the bone. The test was conducted on three separate shoulder models using three different lateral Bio-Tenodesis screws. Dr. Pizilali's report is attached to my report as Ex. 37. This testing confirms that a tension force is applied to the suture after the suture eyelet is placed at the bottom of the bone hole. This test confirmed what I suspected to be true based on my 22 years of experience with attaching suture to suture anchors in bone; that the suture is tensioned as it is moving through the suture eyelet at the bottom of the bone hole. I then inserted the anchor body (screw) to wedge the suture between the anchor body and the bone and completed the simulated repair.

**B. Testing Conducted on the Millett Work**

This testing was conducted to determine whether there is a tension force applied to the suture threaded through a first (medial) and second (lateral) Corkscrew anchor as a knot is being tied in the suture to compress tissue to bone. A strand of FiberWire suture was threaded through a suture loop tied to the load cell to simulate the first (medial) Corkscrew anchor. I then passed both loose ends of FiberWire suture through the tissue so that the suture was on top of the tissue. I then formed a hole for the second (lateral) 5.0mm Corkscrew anchor using a drill bit and a tap. I then inserted the lateral Corkscrew anchor into the sawbone. I then passed the suture attached to the load cell through the eyelet of the second anchor as Dr. Millett describes in his article.

*See, e.g.,* Figs. 3-4 of the Millett Article (Ex. 24). I then began to tie a knot in the suture on top of the tissue to compress the tissue back to the bone. As I was tying the knot, Dr. Piziali was checking whether there was any measureable tension force on the suture. He measured a tension force while I was forming and then tightening the knot. This test was performed on three different shoulder models and three different lateral Corkscrew anchors. Dr. Piziali's report is attached to my report as Ex. 37.

This testing confirmed my opinion that a tension force is applied to the suture as the knot is being tied in order to compress the tissue back to the bone, and that the tension is applied to the suture after the anchor is inserted into bone. I then finished tying the knot and locked it in place with half-hitches to secure the suture to the second (lateral) Corkscrew anchor.

## **IX. OPINIONS**

### **A. Anticipation and Obviousness**

I understand that a prior art reference anticipates a claim if each limitation of the claim is shown in the prior art reference. I also understand if the difference between a prior art reference,

or the combination of two or more prior art references, would have been obvious to a person of ordinary skill in the art, the invention is not patentable.

I have also been informed that a combination of references is obvious if the specific teachings within each reference is familiar to the person of ordinary skill and the combination of references would yield predictable results. I also understand that if a person of ordinary skill is motivated to make variations to what was already known in the art (e.g., by design incentives, market demands, etc.) and those variations are predictable, then the result is an obvious variation over the known state of the art at the time. I further understand that if a combination is nothing more than the predictable use of prior art devices combined and used the same way they are normally used, then the combination is obvious.

I also understand the question for obviousness is what inferences and creative steps would the person of ordinary skill in the art employ in light of the known prior art. If the combination of references results in a process with commonly understood benefits such as, for example, being faster, or easier, then there is a motivation to combine those references even where there is no explicit suggestion in the references themselves to do so. I understand this is because the desire to enhance commercial opportunities by improving a product or process is universal and common-sense.

I further understand that factors such as i) long-felt, but unsolved need, ii) failure of others and iii) unexpected results can be indications that an invention is not obvious. It is my opinion that none of these factors exist in the case of KFx's construct. First, there was not any long-felt but unsolved need. In fact, the progression in going from Dr. Millett's knotted anchor construct during 2003 to Dr. ElAttrache's, or KFx's, construct took a mere matter of months.

Second, I have no reason to believe this was a situation where others had attempted to solve a problem but failed. Rather, the progression from Dr. Millett's knotted construct to Dr. ElAttrache's and/or KFx's knotless construct was second nature to a person of ordinary skill in the art. Adding a knotless anchor would create a faster and more efficient surgical procedure. And adding the specific anchor used by Dr. ElAttrache, the Bio-Tenodesis screw, was a logical choice for Dr. ElAttrache since he is one of the inventors on the ElAttrache '281 Patent and he assisted with the design of that anchor.

Third, it is my opinion that the results achieved by KFx, and Dr. ElAttrache, were not unexpected. Rather, they were exactly the results a person of ordinary skill in the art would expect to receive by plugging in the specific knotless anchors used in place of the knotted anchors used, for example, in Dr. Millett's work. The knotless anchors would be used the same way whether they were used in a double row construct, as they were, or a construct in which the suture was not attached to a first anchor, but rather, attached directly to the tissue. It is my opinion that the results were predictable and what one would expect.

It is also my opinion that the fact that both KFx and Dr. ElAttrache (along with Arthrex) were working on a linked double row construct using knotless anchors indicates that the construct was obvious to a person of ordinary skill in the art. Multiple parties working on virtually the same idea is consistent with the idea being a natural step a person of ordinary skill in the art would have taken in light of the state of the art at the time.

#### B. Written Description, Enablement and Best Mode

I understand that in order for a claim to be valid it must be supported by a written description explaining the manner and process of making and using it and in such full, clear, concise, and exact terms as to enable any person skilled in the art to make and use the invention.

I also understand the written description must describe the inventor's best mode for carrying out the invention.

C. Person of Ordinary Skill in the Art

As I previously stated in connection with claim construction, I believe that a person of ordinary skill at the time of the invention, in the 2004 time frame, would have been an orthopedic surgeon with several years of experience or an engineer with several years of experience in developing and designing orthopedic surgical methods and instruments. Both would have an understanding of surgical procedures, including rotator cuff surgical procedures and both would have an understanding of the different types of suture anchors available on the market and of the different types of constructs available for repairing soft tissue.

D. Court's Claim Construction

My opinions are based on my understanding of the Court's construction of the claim terms as described in the Order dated October 10, 2012. Ex. 38.

E. Examiner's Reasons for Allowance

I reviewed the prosecution history of the '311 Patent and understand that the combination of the Thal '168 Patent and U.S. Patent No. 5,634,926 to Jobe ("the Jobe '926 Patent) (Ex. 39) were applied by the examiner in rejecting the pending claims. According to the examiner, the Thal '168 Patent teaches inserting a first anchor 26 into bone 28, where the first anchor is positioned underneath the soft tissue 30. Ex. 9 at KFX 1960. The examiner also stated that the Thal '168 Patent teaches passing a first length of suture 42 from the first anchor over the soft tissue 30 and inserting a second anchor 24 into bone laterally to the soft tissue. Ex. 9 at KFX 1960. The examiner also stated that the Jobe '926 Patent teaches anchors being positioned

beyond an edge of the soft tissue such that it is not underneath the soft tissue. Ex. 9 at KFX 1960.

The examiner allowed the claims of the '311 Patent over the Thal '168 Patent and the Jobe '926 Patent because the examiner believed the combination of those references did not teach the ordering of steps required by the claims; after inserting the second anchor, tensioning the first length of suture to compress an area of tissue to bone between the edge of the soft tissue and the first anchor. No other reasons for allowing the claims were given by the examiner. Ex. 9 at KFX 1992-93. And the examiner gave the same exact reasons for allowing the claims in the '942 and '969 Patents. Ex. 10 at KFX 32710; Ex. 11 at KFX 33036.

I believe this limitation the examiner stated was missing from the combination of the Thal '168 Patent and the Jobe '926 Patent is disclosed in at least three other references; the ElAttrache/Arthrex work; the Millett work; and the Greenfield '835 Patent. It is also my opinion that had the examiner applied any one of these other references, he would not have allowed the claims of the KFx Patents.

I also believe the examiner would have applied each one of these references to reject the claims at least because each reference is directed to the field of reattaching tissue to bone, just like the Thal '168 Patent and the Jobe '926 Patent, and also because the combination of references would have yielded predictably successful results.

#### 1. The ElAttrache/Arthrex Work

As described above, the ElAttrache/Arthrex Work shows that the second anchor is inserted into the bone then the suture is tensioned. This is shown by the suture eyelet of the Bio-Tenodesis Screw at the end of the driver being placed into the bone hole, then the suture from the first (medial) anchor threaded through the suture loop is tensioned. Supra at 9-16. Dr. Piziali's

testing also confirmed this. Since the examiner believed it was appropriate to combine the Thal ‘168 Patent with the Jobe ‘926 Patent, I believe the examiner would also have considered it appropriate to combine the ElAttrache/Arthrex Work with those same references in rejecting the claims. For example, the ElAttrache/Arthrex Work shows more of the limitations of the KFx Patent claims than does the portion of the Jobe ‘926 Patent relied upon by the examiner (Ex. 39 at Figure 9 and column 8, lines 34-37), which describes an anchor positioned beyond an edge of the soft tissue connected to the soft tissue by suture. Therefore, it is my opinion that the examiner would have combined the ElAttrache/Arthrex Work with both the Thal ‘168 Patent and the Jobe ‘926 Patent to reject the claims of the KFx Patents.

## 2. The Millett Work

As described above, the Millett Work shows that the second anchor is inserted into the bone then the suture threaded through the eyelet of the first and second anchors is tensioned while the knot is being formed and tightened. Supra at 16-20. Dr. Piziali’s test also confirms this. I believe the examiner would have considered it appropriate to combine the Millett Work with the Thal ‘168 Patent and the Jobe ‘926 Patents because the Millett Work is directed to reattaching tissue to bone and also because the Millett Work looks like the bridged double row construct described in the KFx Patents. The Millett Work shows a medial anchor underneath the soft tissue and a lateral anchor beyond an edge of the soft tissue where the suture connecting the two anchors extends from the first anchor to the edge of the soft tissue so as to create a compression force from the soft tissue to bone to promote healing. The Millett Work also shows a four-anchor construct with two medial anchors and two lateral anchors and the suture strands crossed over each other. These are the same types of constructs described in the KFx Patents, except that knots are tied in the suture, so I believe the examiner would have applied it in

rejecting the claims. The examiner already knew knotless anchors were used with a bridged double row construct as described in the Thal '168 Patent.

### 3. The Greenfield '835 Patent

As described above, the Greenfield '835 Patent shows a knotless anchor that captures suture in between two portions of the anchor; an anchor base and an anchor cap. Supra at 21-23. The Greenfield '835 Patent also shows that the anchor base is inserted into bone, then the suture is tensioned and then the anchor cap is advanced into the anchor base to capture the suture between the two anchor portions. Supra at 21-23. I believe the examiner would have combined the Greenfield '835 Patent with the other two references because they are all directed to reattaching tissue to bone and also because the Greenfield '835 Patent describes a two-piece knotless anchor that captures suture the same way as the lateral anchor described in the KFx Patents. The examiner had already combined a non-bridged suture anchor (the Jobe '926 Patent) with a bridged construct (the Thal '168 Patent) and since the Greenfield '835 Patent is the same type of anchor as described in the KFx Patents, I believe the examiner would have applied it in rejecting the claims.

### F. The '311 Patent

Based on my review of the prior art and the asserted claims of the '311 Patent, as interpreted by the Court, it is my opinion that the ElAttrache/Arthrex Work anticipates asserted claims 1, 5-7, 11, 12, 14-21, 23-25 and 28-30 of the '311 Patent because it includes every limitation of each of those claims. To the extent that the ElAttrache/Arthrex Work does not anticipate any of the asserted claims, it would have been obvious to add any of the references discussed above or in the Appendices to the ElAttrache/Arthrex Work for the reasons stated below.

It is also my opinion that each of the asserted claims of the '311 Patent is invalid because it would have been obvious to a person of ordinary skill in the art in the 2004-2005 timeframe to combine various features of: i) the ElAttrache/Arthrex Work, ii) the Millet work, iii) the Thal '168 Patent, iv) the ElAttrache '281 Patent, v) the Burkhardt '272 Patent, vi) the Greenfield '835 Patent, vii) the Guanche Work and/or other prior art references, and arrive at the limitations of the asserted claims.

It is further my opinion that claim 24 (and any claims that depend from claim 24) is invalid because it is not supported by a sufficient written description that would enable a person of ordinary skill in the art to make and use the invention and also because the inventors did not describe their best mode.

Exemplary bases for my opinions are included below for each asserted claim of the '311 Patent. More complete and additional bases supporting my opinions are included in the claim charts attached to my report at Appendices 1-4.

1. Claim 1 of the '311 Patent

a. Anticipation

The ElAttrache/Arthrex Work includes every limitation of claim 1 of the '311 Patent. It includes a method of attaching soft tissue to bone comprising: inserting a first anchor into bone, where the first anchor is positioned underneath the soft tissue such that no part of the anchor extends beyond an edge of the soft tissue. The ElAttrache/Arthrex Work is a method of attaching soft tissue to bone. The other limitations of claim 1 are shown, for example, by the insertion of the Corkscrew anchor underneath the simulated tissue. *Supra* at 9-16.<sup>5</sup> The

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<sup>5</sup> I do not believe that any of the accused procedures insert the first anchor into bone underneath the soft tissue as it is described and claimed in the KFx Patents. The KFx Patents always describe the medial anchor as piercing the soft tissue. However, in the accused procedures the soft tissue is always removed so that the medial anchors are inserted directly into

ElAttrache/Arthrex Work also includes passing a first length of suture from the first anchor over the soft tissue, for example, when the suture is passed through the tissue to the top side of the tissue. Supra at 9-16. The ElAttrache/Arthrex Work further includes inserting a second anchor in the bone where the second anchor is positioned beyond the edge of the soft tissue and not underneath the soft tissue. This is shown when the suture eyelet at the end of the Bio-Tenodesis driver is placed into the bone hole. Supra at 9-16. The Athrex/ElAttrache Work also includes after inserting the second anchor, tensioning the first length of suture to compress an area of tissue to bone between the edge of the soft tissue and the first anchor. This is shown when the suture threaded through the suture eyelet is tensioned with the suture eyelet at the tip of the driver at the bottom of the bone hole. Supra at 9-16. The ElAttrache/Arthrex Work also discloses fixedly securing the first length of suture to the second anchor without tying any knots. This is shown when the Bio-Tenodesis screw anchor body is screwed into the bone hole and wedges the suture between the anchor body and the bone wall. Supra at 9-16.<sup>6</sup>

b. Obviousness

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bone without going through the tissue. The medial anchors used in the accused methods are larger in diameter than the “nail” type anchor described in the KFx Patents. A surgeon would not pierce the tissue with the larger diameter anchors promoted for use in the accused methods because it would damage the tissue. However, for purposes of this report, I have been asked to assume KFx’s apparent position that the method of inserting the medial anchors in the accused methods meets this claim limitation. Accordingly, the cited prior art that inserts a medial anchor all meet this limitation, regardless of whether the medial anchor is inserted through the tissue or directly into the bone.

<sup>6</sup> I have reviewed KFx’s infringement contentions and understand that it is KFx’s position that by wedging the suture between the anchor body and the bone wall in the accused anchors (PushLock and SwiveLock) the suture is fixedly secured to the second anchor without tying any knots. I disagree. With regard to SutureBridge, a medial knot is required to prevent the suture from slipping past the second (lateral) anchor. I also understand that Michael Green, one of KFx’s inventors, did not consider wedging the suture between the lateral anchor body and the bone wall to be part of his invention because he did not believe it would work. Ex. 40 at 216-19. However, for purposes of this report, I have been asked to assume that wedging the suture between the lateral anchor body and the bone wall is fixedly securing the suture to the second anchor without tying any knots.

It would have been obvious, in view of the above-identified prior art references, to combine different features of those references and arrive at the limitations of this claim. For example, the Millett work describes inserting a first anchor into bone underneath the soft tissue. Supra at 16-20. It also shows passing a length of suture from the first anchor over the soft tissue. Supra at 16-20. The Millett work also shows inserting a second anchor into bone beyond an edge of the soft tissue so that it is not underneath the soft tissue. Supra at 16-20. Millett also shows tensioning the suture after the second anchor is inserted into bone. Supra at 16-20. Millett also shows fixedly securing the suture to the second anchor, however, a knot is tied. Supra at 16-20. Knotless anchors were well known in the art at the time (supra at 26-28, 28-30) including two-piece knotless anchors very similar to the lateral anchor described in the '311 Patent. Supra at 21-23. And as shown in the Thal '168 Patent, it was also well known to use knotless suture anchors in a double row construct where the suture is bridged between a lateral and a medial anchor. Supra at 20-21.

Since both the Millett work and the Thal '168 Patent are in the same field of attaching tissue to bone using suture anchors, it is my opinion that a person of ordinary skill in the art would have been motivated to combine the two references and arrive at the claimed invention. The examiner already combined two such prior art references (the 'Thal 168 Patent and the Jobe '926 Patent) in rejecting the claims.

At the time of the invention, the Millett work was already well known in the field of orthopedics. Dr. Millett's presentation at the World Wide Surgeon's Meeting on January 10, 2004, exposed his work to hundreds of prominent surgeons throughout the country as well as sales representatives. As normally occurs after such presentations, Dr. Millett's work was most certainly shared almost immediately with other surgeons and sales representatives around the

country, and the world. Thus, soon after the WWSM, Dr. Millett's work would have been common knowledge in the orthopedic field.

A person of ordinary skill in the art would also have recognized that the Millett work required knots to be tied. Since knotless anchors were well known in the art and were also known to be used in double row suture bridge constructs, an orthopedic surgeon would have realized almost instantly that knotless anchors could replace the knotted anchors. A knotless construct would have been highly desirable since tying knots arthroscopically is relatively difficult to do for many surgeons and an easier and more repeatable way to conduct the surgery would have been highly sought after.

I have also reviewed the deposition testimony of Michael Green, one of the inventors of the KFx Patents, in which he states that during the 2004 timeframe it would have been obvious to him to add a knotless anchor to a construct in which two knotted anchors are linked by a strand of suture. Ex. 40 at 96-97. This further supports my opinion that it would have been obvious to a person of ordinary skill to add knotless anchors to the Millett work and arrive at the claimed method.

2. Claim 5 of the '311 Patent

a. Anticipation

The ElAttrache/Arthrex Work includes every limitation of claim 5 of the '311 Patent. Claim 5 depends from claim 1 and further includes inserting a third anchor into bone where the third anchor is positioned beyond an edge of the soft tissue such that it is not underneath the soft tissue. This is shown in the ElAttrache/Arthrex Work where a second lateral Bio-Tenodesis Screw is inserted into bone. Supra at 9-16.

b. Obviousness

It would have been obvious, in view of the above-identified prior art references, to combine different features of those references and arrive at the limitations of this claim. For example, the Millett work describes inserting a third anchor into bone beyond an edge of the soft tissue and not underneath the soft tissue. Supra at 16-20. The Thal '168 Patent also shows a third anchor inserted into bone where that anchor may be inserted either under the tissue or lateral to the tissue. Supra at 20-21. And as the examiner pointed out, the Jobe '926 Patent also shows an anchor inserted into bone beyond an edge of the soft tissue so that it is not underneath the soft tissue. Supra at 36-37. For the same reasons mentioned above, it would have been obvious to combine these features of the Millett work, the Thal '168 Patent and/or the Jobe '926 Patent with the prior art references mentioned above for claim 1 and arrive at the limitations of this claim.

I also believe it would have been obvious to have a third anchor inserted into bone beyond an edge of the soft tissue because multiple medial and multiple lateral anchors were already well known constructs for use in rotator cuff repair in the 2004 timeframe. An orthopedic surgeon would have instantly known that the more anchors used the better the compression of the soft tissue back to the bone.

3. Claim 6 of the '311 Patent

a. Anticipation

The ElAttrache/Arthrex Work includes every limitation of claim 6 of the '311 Patent. Claim 6 depends from claim 5 and further includes passing a second length of suture from the first anchor over the soft tissue. This is shown in the ElAttrache/Arthrex Work where a second length of suture is passed from the first medial Corkscrew anchor over the soft tissue. Supra at 9-16.

b. Obviousness

It would have been obvious, in view of the above-identified prior art references, to combine different features of those references and arrive at the limitations of this claim. For example, the Millett work describes passing a second length of suture from the first anchor over the soft tissue. *Supra* at 16-20. The Thal '168 Patent also shows two lengths of suture passed from the first anchor over the soft tissue. *Supra* at 20-21. For the same reasons mentioned above, it would have been obvious to combine these features of the Millett work and/or the Thal '168 Patent with the prior art references mentioned above for claim 5 and arrive at the limitations of this claim.

4. Claim 7 of the '311 Patent

a. Anticipation

The ElAttrache/Arthrex Work includes every limitation of claim 7 of the '311 Patent. Claim 7 depends from claim 6 and further includes fixedly securing the second length of suture to the third anchor without tying any knots. This is shown in the ElAttrache/Arthrex Work where a second length of suture is wedged between the second lateral anchor body and the bone wall. *Supra* at 9-16.

b. Obviousness

It would have been obvious, in view of the above-identified prior art references, to combine different features of those references and arrive at the limitations of this claim. For example, knotless anchors were well known in the art at the time (*supra* at 26-28, 28-30) including two-piece knotless anchors very similar to the lateral anchor described in the '311 Patent. *Supra* at 21-23. And as shown in the Thal '168 Patent, it was also well known to use knotless suture anchors in a double row construct where the suture is bridged between a lateral

and a medial anchor. Supra at 20-21. For the same reasons mentioned above, it would have been obvious to combine the knotless anchors with the prior art references mentioned above for claim 6 and arrive at the limitations of this claim.

5. Claim 11 of the '311 Patent

a. Anticipation

The ElAttrache/Arthrex Work includes every limitation of claim 11 of the '311 Patent. Claim 11 depends from claim 1 and includes inserting a third anchor in bone where the third anchor is positioned underneath the soft tissue at a location distinct from the first anchor. This is shown in the ElAttrache/Arthrex Work where a second medial anchor is inserted into the bone underneath the soft tissue. Supra at 9-16. This is also shown in the ElAttrache/Arthrex Work describing a linked double row construct with suture from two medial anchors being connected in a knotless fashion to two lateral anchors in a criss-cross pattern. Supra at 9-16.

b. Obviousness

It would have been obvious, in view of the above-identified prior art references, to combine different features of those references and arrive at the limitations of this claim. For example, the Millett work shows the insertion of a third anchor in bone and underneath the soft tissue in a position distinct from the first anchor. Supra at 16-20. The Thal '168 Patent also shows a third anchor inserted into bone where the anchor may be inserted under the tissue or adjacent to the tissue. Supra at 20-21. It also would have been obvious to an orthopedic surgeon at the time to add anchors and suture strands to the construct to strengthen the repair by adding compression over a larger footprint. For the same reasons mentioned above, it would have been obvious to combine these references showing a third anchor inserted into bone and under the

tissue with the prior art references mentioned above for claim 1 and arrive at the limitations of this claim.

6. Claim 12 of the '311 Patent

a. Anticipation

The ElAttrache/Arthrex Work includes every limitation of claim 12 of the '311 Patent. Claim 12 depends from claim 11 and includes passing a second length of suture from the third anchor over the soft tissue. This is shown in the ElAttrache/Arthrex Work where a second length of suture is passed over the soft tissue from the second medial anchor. Supra at 9-16. This is also shown in the ElAttrache/Arthrex Work describing a linked double row construct with suture from two medial anchors being connected in a knotless fashion to two lateral anchors in a criss-cross pattern. Supra at 9-16.

b. Obviousness

It would have been obvious, in view of the above-identified prior art references, to combine different features of those references and arrive at the limitations of this claim. For example, the Millett work shows passing a second length of suture from the third anchor over the soft tissue. Supra at 16-20. The Thal '168 Patent also shows a second length of suture from the third anchor being passed over the soft tissue. Supra at 20-21. It also would have been obvious to an orthopedic surgeon at the time to add anchors and suture strands to the construct to strengthen the repair by adding compression over a larger footprint.

For the same reasons mentioned above, it would have been obvious to combine these references showing a second length of suture being passed over the soft tissue with the prior art references mentioned above for claim 11 and arrive at the limitations of this claim.

7. Claim 14 of the '311 Patent

a. Anticipation

The ElAttrache/Arthrex Work includes every limitation of claim 14 of the '311 Patent.

Claim 14 depends from claim 12 and includes fixedly securing the second length of suture to the second anchor without tying any knots. This is shown in the ElAttrache/Arthrex Work where the second length of suture from the second medial anchor is fixedly secured to the lateral anchor.

Supra at 9-16. This is also shown in the ElAttrache/Arthrex Work describing a linked double row construct with suture from two medial anchors being connected in a knotless fashion to two lateral anchors in a criss-cross pattern. Supra at 9-16.

b. Obviousness

It would have been obvious, in view of the above-identified prior art references, to combine different features of those references and arrive at the limitations of this claim. For example, the Millett work shows fixedly securing the second length of suture to the second anchor. Supra at 16-20. It also would have been obvious to an orthopedic surgeon at the time to add anchors and suture strands to the construct to strengthen the repair by adding compression over a larger footprint.

And although knots are tied in the Millett work it would have been obvious to combine it with any one of a number of knotless suture anchors known at the time including the knotless anchors used in the ElAttrache/Arthrex Work (supra at 9-16), the knotless anchors used in the Thal '168 Patent (supra at 20-21), the knotless anchor shown in the Greenfield '835 Patent (supra at 21-23) among several others well known at the time. For the same reasons mentioned above, it would have been obvious to combine these references showing fixedly securing the second length of suture to the second anchor without tying any knots with the prior art references mentioned above for claim 12 and arrive at the limitations of this claim.

8. Claim 15 of the '311 Patent

a. Anticipation

The ElAttrache/Arthrex Work includes every limitation of claim 15 of the '311 Patent. Claim 15 depends from claim 14 and includes inserting a fourth anchor in the bone where the fourth anchor is positioned beyond the edge of the soft tissue so that it is not underneath the soft tissue and at a location distinct from the second anchor. This is shown in the ElAttrache/Arthrex Work where a second lateral anchor is inserted into the bone. Supra at 9-16. This is also shown in the ElAttrache/Arthrex Work describing a linked double row construct with suture from two medial anchors being connected in a knotless fashion to two lateral anchors in a criss-cross pattern. Supra at 9-16.

b. Obviousness

It would have been obvious, in view of the above-identified prior art references, to combine different features of those references and arrive at the limitations of this claim. For example, the Millett work shows the insertion of a fourth anchor in the bone beyond an edge of the soft tissue and at a location distinct from the second anchor. Supra at 16-20. It also would have been obvious to an orthopedic surgeon at the time to add anchors and suture strands to the construct to strengthen the repair by adding compression over a larger footprint.

For the same reasons mentioned above, it would have been obvious to combine these references showing the insertion a fourth anchor in the bone beyond an edge of the soft tissue and at a location distinct from the second anchor with the prior art references mentioned above for claim 14 and arrive at the limitations of this claim.

9. Claim 16 of the '311 Patent

a. Anticipation

The ElAttrache/Arthrex Work discloses every limitation of claim 16 of the '311 Patent.

Claim 16 depends from claim 15 and includes passing a third length of suture from the third anchor over the soft tissue and the first length of suture. This is shown in the ElAttrache/Arthrex Work where a length of suture is passed from the second medial anchor over the soft tissue and crosses over the first length of suture. Supra at 9-16. This is also shown in the ElAttrache/Arthrex Work describing a linked double row construct with suture from two medial anchors being connected in a knotless fashion to two lateral anchors in a criss-cross pattern. Supra at 9-16.

b. Obviousness

It would have been obvious, in view of the above-identified prior art references, to combine different features of those references and arrive at the limitations of this claim. For example, the Millett work shows passing a third length of suture from the third anchor over the soft tissue and the first length of suture. Supra at 16-20. It also would have been obvious to an orthopedic surgeon at the time to add anchors and suture strands to the construct to strengthen the repair by adding compression over a larger footprint.

For the same reasons mentioned above, it would have been obvious to combine this reference showing passing a third length of suture from the third anchor over the soft tissue and the first length of suture with the prior art references mentioned above for claim 15 and arrive at the limitations of this claim.

10. Claim 17 of the '311 Patent

a. Anticipation

The ElAttrache/Arthrex Work includes every limitation of claim 17 of the '311 Patent. Claim 17 depends from claim 16 and includes fixedly securing the third length of suture to the

fourth anchor. This is shown in the ElAttrache/Arthrex Work where the suture from the second medial anchor is wedged between the anchor body of the second lateral anchor and the bone wall. Supra at 9-16. This is also shown in the ElAttrache/Arthrex Work describing a linked double row construct with suture from two medial anchors being connected in a knotless fashion to two lateral anchors in a criss-cross pattern. Supra at 9-16.

b. Obviousness

It would have been obvious, in view of the above-identified prior art references, to combine different features of those references and arrive at the limitations of this claim. For example, the Millett work shows fixedly securing the third length of suture to the fourth anchor. Supra at 16-20. It also would have been obvious to an orthopedic surgeon at the time to add anchors and suture strands to the construct to strengthen the repair by adding compression over a larger footprint.

For the same reasons mentioned above, it would have been obvious to combine this reference showing fixedly securing the third length of suture to the fourth anchor with the prior art references mentioned above for claim 16 and arrive at the limitations of this claim.

11. Claim 18 of the '311 Patent

a. Anticipation

The ElAttrache/Arthrex Work includes every limitation of claim 18 of the '311 Patent. Claim 18 depends from claim 17 and includes passing a fourth length of suture from the first anchor over the soft tissue. This is shown in the ElAttrache/Arthrex Work where a second suture strand attached to the first medial anchor is passed over the soft tissue. Supra at 9-16. This is also shown in the ElAttrache/Arthrex Work describing a linked double row construct with suture

from two medial anchors being connected in a knotless fashion to two lateral anchors in a criss-cross pattern. Supra at 9-16.

b. Obviousness

It would have been obvious, in view of the above-identified prior art references, to combine different features of those references and arrive at the limitations of this claim. For example, the Millett work shows passing a fourth length of suture from the first anchor over the soft tissue. Supra at 16-20. It also would have been obvious to an orthopedic surgeon at the time to add anchors and suture strands to the construct to strengthen the repair by adding compression over a larger footprint.

For the same reasons mentioned above, it would have been obvious to combine this reference showing passing a fourth length of suture from the first anchor over the soft tissue with the prior art references mentioned above for claim 17 and arrive at the limitations of this claim.

12. Claim 19 of the '311 Patent

a. Anticipation

The ElAttrache/Arthrex Work includes every limitation of claim 19 of the '311 Patent. Claim 19 depends from claim 18 and includes fixedly securing the fourth length of suture to the fourth anchor. This is shown in the ElAttrache/Arthrex Work where the second strand of suture attached to the first medial anchor is wedged between the anchor body of the second lateral anchor and the bone wall. Supra at 9-16. This is also shown in the ElAttrache/Arthrex Work describing a linked double row construct with suture from two medial anchors being connected in a knotless fashion to two lateral anchors in a criss-cross pattern. Supra at 9-16.

b. Obviousness

It would have been obvious, in view of the above-identified prior art references, to combine different features of those references and arrive at the limitations of this claim. For example, the Millett work shows fixedly securing the fourth length of suture to the fourth anchor. Supra at 16-20. It also would have been obvious to an orthopedic surgeon at the time to add anchors and suture strands to the construct to strengthen the repair by adding compression over a larger footprint.

For the same reasons mentioned above, it would have been obvious to combine this reference showing fixedly securing the fourth length of suture to the fourth anchor with the prior art references mentioned above for claim 18 and arrive at the limitations of this claim.

13. Claim 20 of the '311 Patent

a. Anticipation

The ElAttrache/Arthrex Work includes every limitation of claim 20 of the '311 Patent. Claim 20 depends from claim 1 and includes inserting a third anchor into bone underneath the soft tissue at a location distinct from the first anchor, inserting a fourth anchor into bone beyond an edge of the soft tissue such that it is not underneath the soft tissue at a location distinct from the second anchor, passing a second length of suture from the third anchor over the soft tissue and the first length of suture, and fixedly securing the second length of suture to the fourth anchor. This is shown in the ElAttrache/Arthrex Work where two medial anchors and two lateral anchors are inserted into bone, and where a strand of suture is passed from the second medial anchor over the soft tissue and over the strand of suture connecting the first medial anchor and the first lateral anchor, and where that strand of suture is wedged between the anchor body of the second lateral anchor and the bone. Supra at 9-16. This is also shown in the ElAttrache/Arthrex

Work describing a linked double row construct with suture from two medial anchors being connected in a knotless fashion to two lateral anchors in a criss-cross pattern. Supra at 9-16.

b. Obviousness

It would have been obvious, in view of the above-identified prior art references, to combine different features of those references and arrive at the limitations of this claim. For example, the Millett work shows two medial anchors and two lateral anchors inserted into bone where a strand of suture is passed from the second medial anchor over the soft tissue and over the strand of suture connecting the first medial anchor and the first lateral anchor, and where the strand of suture is fixedly secured to the second lateral anchor. Supra at 16-20. It also would have been obvious to an orthopedic surgeon at the time to add anchors and suture strands to the construct to strengthen the repair by adding compression over a larger footprint.

For the same reasons mentioned above, it would have been obvious to combine this reference showing these features with the prior art references mentioned above for claim 1 and arrive at the limitations of this claim.

14. Claim 21 of the '311 Patent

a. Anticipation

The ElAttrache/Arthrex Work includes every limitation of claim 21 of the '311 Patent. Claim 21 depends from claim 1 and requires that the first anchor be directly pierced into bone without drilling any holes. This is shown in the ElAttrache/Arthrex Work where a Corkscrew anchor is inserted into a bone hole formed by a punch and/or tap. Corkscrew anchors do not require drilling a hole to be inserted into bone. Supra at 9-16.

b. Obviousness

It would have been obvious, in view of the above-identified prior art references, to combine different features of those references and arrive at the limitations of this claim. For example, the Millett work shows the Corkscrew anchors as the first anchors which are directly pierced into bone without drilling any holes. Supra at 16-20. For the same reasons mentioned above, it would have been obvious to combine this reference showing these features with the prior art references mentioned above for claim 1 and arrive at the limitations of this claim.

15. Claim 23 of the '311 Patent

a. Anticipation

The ElAttrache/Arthrex Work includes every limitation of claim 23 of the '311 Patent. Claim 23 depends from claim 1 and requires passing the length of suture over the soft tissue without the suture being coupled to the second anchor. This is shown in the ElAttrache/Arthrex Work where the suture is passed over the soft tissue before it is threaded through the suture eyelet at the end of the driver for the Bio-Tenodesis Screw. Supra at 9-16.

b. Obviousness

It would have been obvious, in view of the above-identified prior art references, to combine different features of those references and arrive at the limitations of this claim. For example, the Millett work shows passing the length of suture over the soft tissue without the suture being coupled to the second anchor. Supra at 16-20. The Thal '168 Patent also shows passing the length of suture over the soft tissue without the suture being coupled to the second anchor. Supra at 20-21. For the same reasons mentioned above, it would have been obvious to combine these references showing these features with the prior art references mentioned above for claim 1 and arrive at the limitations of this claim.

16. Claim 24 of the '311 Patent

a. Anticipation

The ElAttrache/Arthrex Work includes every limitation of claim 24 of the '311 Patent. Claim 24 depends from claim 1 and requires that the suture be coupled to the second anchor prior to insertion and where after inserting the second anchor, the suture is tensioned and then fixedly secured to the second anchor. This is shown in the ElAttrache/Arthrex Work where the suture is threaded through the suture eyelet at the end of the Bio-Tenodesis driver prior to the suture eyelet being placed in the bone hole. After the suture eyelet is inserted, the suture from the first anchor is tensioned and slides through the suture eyelet. Then the anchor body is screwed into the hole wedging the suture between the anchor body and the bone hole. Supra at 9-16.

b. Obviousness

It would have been obvious, in view of the above-identified prior art references, to combine different features of those references and arrive at the limitations of this claim. For example, the Millett work combined with any one of the known knotless anchors at the time include all of the limitations of claim 1. And combining the Millett work with, for example, the Burkhardt '272 Patent or the ElAttrache '281 Patent, includes the limitations of this claim since both of those anchors have eyelets through which the suture is threaded prior to the eyelet being placed into the bone hole. Supra at 26-28 and 28-30. For the same reasons mentioned above, it would have been obvious to combine these references showing these features with the prior art references mentioned above for claim 1 and arrive at the limitations of this claim.

c. Lack of Written Description, Enablement and Best Mode

I do not believe the specification of the KFx Patents includes a sufficient written description to enable a person of ordinary skill in the art to make and use a second anchor in

which suture is coupled to the second anchor prior to it being inserted into the bone. The only description of a second anchor in the specification is the two-piece second anchor. There is no description about how the suture would be coupled to the two-piece second anchor prior to the anchor being inserted into the bone.<sup>7</sup> I cannot visualize how the suture would be coupled to the two-piece anchor prior to being inserted into bone because the only time the suture is touching the second anchor is when it is being tensioned and then captured between the two anchor portions, and both occur only after the second anchor has already been inserted. Since there is no description of how to achieve this, there is also no description of what the inventors believed to be their best mode for achieving it.

17. Claim 25 of the '311 Patent

a. Anticipation

The ElAttrache/Arthrex Work includes every limitation of claim 25 of the '311 Patent. Claim 25 depends from claim 1 and requires that the second anchor be inserted directly into bone without passing through the soft tissue. This is shown in the ElAttrache/Arthrex Work where the suture eyelet at the end of the Bio-Tenodesis driver is placed directly into the bone hole without passing through the soft tissue. Supra at 9-16.

b. Obviousness

It would have been obvious, in view of the above-identified prior art references, to combine different features of those references and arrive at the limitations of this claim. For example, the Millett work shows that the second anchor is inserted directly into bone without

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<sup>7</sup> There is a sentence in the specification stating that "in one embodiment, the suture may be coupled to the second bone anchor prior to insertion and then fixedly secured after insertion." Ex. 3 at column 13, lines 45-47. This description is insufficient, however, to teach a person of ordinary skill to actually couple the suture to the second anchor prior to insertion. It merely states the goal without explaining how to do it.

passing through the soft tissue. Supra at 16-20. The Thal '168 Patent also shows this same feature. Supra at 20-21. For the same reasons mentioned above, it would have been obvious to combine these references showing these features with the prior art references mentioned above for claim 1 and arrive at the limitations of this claim.

18. Claim 28 of the '311 Patent

a. Anticipation

The ElAttrache/Arthrex Work includes every limitation of claim 28 of the '311 Patent. Claim 28 depends from claim 1 and requires that the inserting, passing and fixedly securing steps be conducted arthroscopically. This is shown in the ElAttrache/Arthrex Work where Dr. ElAttrache performed his surgery arthroscopically on a live patient. Dr. ElAttrache describes this surgery in his surgical report (Ex. 19) and the surgery is also shown in a video through the arthroscope. Ex. 20.

b. Obviousness

It would have been obvious, in view of the above-identified prior art references, to combine different features of those references and arrive at the limitations of this claim. For example, the Millett work is directed to arthroscopic surgery as evidenced by the title of the article ("Mattress Double Anchor Arthroscopic Rotator Cuff Repair"). Supra at 16-20. The Thal '168 Patent also describes the construct for use in arthroscopic surgery. See, e.g., Ex. 28 at column 1, lines 29-38. For the same reasons mentioned above, it would have been obvious to combine these references showing these features with the prior art references mentioned above for claim 1 and arrive at the limitations of this claim.

19. Claim 29 of the '311 Patent

a. Anticipation

The ElAttrache/Arthrex Work includes every limitation of claim 29 of the ‘311 Patent. Claim 29 depends from claim 1 and requires passing the first length of suture over the edge of the soft tissue. This is shown in the ElAttrache/Arthrex Work where the first length of suture is passed over the edge of the soft tissue to the second (lateral) anchor. *Supra* at 9-16.

b. Obviousness

It would have been obvious, in view of the above-identified prior art references, to combine different features of those references and arrive at the limitations of this claim. For example, the Millett work shows passing the first length of suture over the edge of the soft tissue. *Supra* at 16-20. The Guanche work also shows the first length of tissue passed over the edge of the soft tissue. *Supra* at 24-26. For the same reasons mentioned above, it would have been obvious to combine these references showing these features with the prior art references mentioned above for claim 1 and arrive at the limitations of this claim.

20. Claim 30 of the ‘311 Patent

a. Anticipation

The ElAttrache/Arthrex Work includes every limitation of claim 30 of the ‘311 Patent. Claim 30 depends from claim 1 and requires that the first length of suture pass through the soft tissue only once. This is shown in the ElAttrache/Arthrex Work where the first length of suture is passed from the first (medial) anchor to the top of the soft tissue. The suture then passes over the edge of the soft tissue to the second (lateral) anchor without being passed through the soft tissue again. *Supra* at 9-16.

b. Obviousness

It would have been obvious, in view of the above-identified prior art references, to combine different features of those references and arrive at the limitations of this claim. For

example, the Millett work shows that the first length of suture passes through the soft tissue only once. Supra at 16-20. For the same reasons mentioned above, it would have been obvious to combine this reference showing this feature with the prior art references mentioned above for claim 1 and arrive at the limitations of this claim.

G. The '942 Patent

Based on my review of the prior art and the asserted claims of the '942 Patent, as interpreted by the Court, it is my opinion that the ElAttrache/Arthrex Work anticipates asserted claims 1-7 and 11-19 of the '942 Patent because it includes every limitation of each of those claims. To the extent that the ElAttrache/Arthrex Work does not anticipate any of the asserted claims, it would have been obvious to add any of the references discussed above or in the Appendices to the ElAttrache/Arthrex Work for the reasons stated below.

It is also my opinion that each of the asserted claims of the '942 Patent is invalid because it would have been obvious to a person of ordinary skill in the art in the 2004 timeframe to combine various features of: i) the ElAttrache/Arthrex Work, ii) the Millet work, iii) the Thal '168 Patent, iv) the ElAttrache '281 Patent, v) the Burkhardt '272 Patent, vi) the Greenfield '835 Patent, vii) the Guanche Work and/or the other prior art references identified in the claim charts, and arrive at the limitations of the asserted claims. It is further my opinion that claims 16 and 19 (and any claims that depend from claims 16 and 19) are invalid because they are not supported by a sufficient written description that would enable a person of ordinary skill in the art to make and use the invention and also because the inventors did not describe their best mode.

Exemplary bases for my opinions are included below for each asserted claim of the '942 Patent. More complete and additional bases supporting my opinions are included in the claim charts attached to my report at Appendices 5-8.

## 1. Claim 1 of the '942 Patent

## a. Anticipation

The ElAttrache/Arthrex Work includes every limitation of claim 1 of the '942 Patent. It discloses a method of attaching soft tissue to bone. Supra at 9-16. It also shows the insertion of a first anchor by, for example, the insertion of the Corkscrew anchor underneath the simulated tissue. Supra at 9-16. The ElAttrache/Arthrex Work also discloses passing a first length of suture from the first anchor over the soft tissue, for example, when the suture is passed through the tissue to the top side of the tissue. Supra at 9-16. The ElAttrache/Arthrex Work further discloses inserting a distal member of a second anchor into bone where the second anchor has a distal member and a proximal member. This is shown by the use of a Bio-Tenodesis Screw which has a distal member (the suture eyelet at the end of the driver)<sup>8</sup> and a proximal member (the anchor body), where the suture eyelet is placed into the bone hole. Supra at 9-16. The ElAttrache/Arthrex Work also discloses after inserting the distal member tensioning the suture by tensioning the suture threaded through the suture eyelet with the suture eyelet at the bottom of the bone hole. Supra at 9-16. It also discloses after tensioning moving the proximal member toward the distal member thereby fixedly securing the suture at the second anchor position without tying any knots. This is shown when the anchor body is moved toward the suture eyelet by screwing the anchor body into the bone hole and the suture is wedged between the anchor body and the bone wall without tying any knots. Supra at 9-16.<sup>9</sup>

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<sup>8</sup> Assuming KFx's position that the eyelet on the accused products is part of the anchor.

<sup>9</sup> In KFx's contentions, it points to wedging of the suture between the PushLock or SwiveLock anchors and the bone wall to meet this claim limitation. I disagree. I do not believe the plain meaning of the "second anchor position" is between the anchor body and the bone wall. Rather, it is my opinion that a person of ordinary skill in the art in the 2004 timeframe having read the specification would have understood that term to mean the position between the two anchor portions described in the specification of the KFx patents. I also understand that Michael Green, one of the inventors of the KFx patents did not consider wedging the suture between the

b. Obviousness

It would have been obvious, in view of the above-identified prior art references, to combine different features of those references and arrive at the limitations of this claim. For example, the Millett work, the Thal '168 Patent, the Burkhart '272 Patent, the ElAttrache '281 Patent, the Guanche work, among other prior art references, describe a method of attaching soft tissue to bone. Supra at 16-20, 20-21, 26-28 and 28-30. The Millett work and Thal '168 also show the insertion of a first anchor underneath the tissue. Supra at 16-20, 20-21. Those same references, among others, also show passing a first length of suture from the first anchor over the soft tissue, for example, when the suture is passed through the tissue to the top side of the tissue. Supra at 16-20, 20-21.

Inserting a distal member of a second anchor is shown, for example, in the ElAttrache/Arthrex Work, which shows a suture eyelet at the end of the driver positioned at the bottom of the bone hole. Supra at 9-16. This feature is also shown in the Greenfield '835 Patent, which shows an anchor base screwed into bone just like the anchor base of the second anchor described in the KFx Patents. Supra at 21-23. This limitation is also shown in the Burkhart '272 Patent, which discloses many features of the accused PushLock anchors, including a separate eyelet portion and anchor body. Supra at 26-28. These same features are shown in the ElAttrache '281 Patent, which discloses many of the features of the accused Bio-Tenodesis Screw, including a separate suture eyelet and anchor body. Supra at 28-30. These same features are also shown in the Bio-Tenodesis Screw itself, which is an accused product and prior art to the KFx patents.

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anchor body and the bone to be part of the invention. Ex. 40 at 216-19. However, for purposes of this report, I have been asked to assume that KFx's position expressed in its contentions is correct.

These same references also show that the suture is tensioned after the distal portion of the second anchor is inserted into bone. For example, this is shown in the ElAttrache/Arthrex Work (supra at 9-16), the Greenfield '835 Patent (supra at 21-23), the Burkhart '272 Patent (supra at 26-28); the ElAttrache '281 Patent (supra at 28-30); the Guanche work (supra at 24-26), among several other references described in the claim charts.

These same references also show that after tensioning the suture the proximal member is moved toward the distal member to fixedly secure the suture at the second anchor position without tying any knots. This is shown, for example, in the ElAttrache/Arthrex Work when the anchor body is inserted into the bone hole on top of the suture eyelet. This is also shown in the Greenfield '835 Patent when the anchor cap is advanced into the anchor base to wedge the suture between the two anchor portions, just like the second anchor in the KFx Patents. This is also shown in the Burkhart '272 Patent, the ElAttrache '281 Patent and the Guanche work when the anchor body is screwed into the bone to wedge the suture between the anchor body and the bone wall. Supra at 26-28, 28-30, 24-26.

A person of ordinary skill in the art during the 2004 timeframe would have been motivated to combine these references and arrive at the claimed invention because all of the references are in the same field of orthopedic surgery. The examiner already combined two such prior art references (the 'Thal 168 Patent and the Jobe '926 Patent) in rejecting the claims.

2. Claim 2 of the '942 Patent

a. Anticipation

The ElAttrache/Arthrex Work includes every limitation of claim 2 of the '942 Patent. Claim 2 depends from claim 1 and requires the first length of suture be attached to the first

anchor prior to insertion. This is shown by the Corkscrew anchor which is sold with FiberWire suture pre-attached to it and prior to the anchor being inserted. Supra at 9-16.

b. Obviousness

It would have been obvious, in view of the above-identified prior art references, to combine different features of those references and arrive at the limitations of this claim. For example, the Millett work (which also used Corkscrew anchors) and the Thal '168 Patent show that the first length of suture is attached to the first anchor prior to its insertion. Supra at 16-20; supra at 20-21. For the same reasons mentioned above, it would have been obvious to combine these references showing this feature with the prior art references mentioned above for claim 1 and arrive at the limitations of this claim. In addition, it would have been obvious to a person of ordinary skill to attach the suture to the first anchor prior to insertion to eliminate the step of having to attach the suture after the first anchor is inserted.

3. Claim 3 of the '942 Patent

a. Anticipation

The ElAttrache/Arthrex Work includes every limitation of claim 3 of the '942 Patent. Claim 3 depends from claim 1 and requires forming a hole in the bone into which the distal member of the second anchor is inserted. This is shown by the use of either a punch or a drill to pre-form a hole for the second (lateral) anchor. Supra at 9-16.

b. Obviousness

It would have been obvious, in view of the above-identified prior art references, to combine different features of those references and arrive at the limitations of this claim. For example, the Thal '168 Patent shows that a hole is formed in the bone prior to the anchor being inserted. The Burkhardt '272 Patent and the ElAttrache '281 Patent also show a hole being

formed before the eyelet at the end of the driver for the lateral anchor is placed into the bone hole. Supra at 26-28; supra at 28-30. For the same reasons mentioned above, it would have been obvious to combine these references showing this feature with the prior art references mentioned above for claim 1 and arrive at the limitations of this claim.

4. Claim 4 of the '942 Patent

a. Anticipation

The ElAttrache/Arthrex Work includes every limitation of claim 4 of the '942 Patent. Claim 4 depends from claim 1 and includes a first proximally facing surface on the distal member of the second anchor. This is shown by the proximally facing surface of the suture eyelet at the end of the Bio-Tenodesis driver. See Appendices 5-6.

b. Obviousness

It would have been obvious, in view of the above-identified prior art references, to combine different features of those references and arrive at the limitations of this claim. For example, the Greenfield '835 Patent shows a proximally facing portion of the anchor base. Supra at 21-23. The Burkhardt '272 Patent shows an eyelet implant 50, which has a proximally facing surface, touching inner shaft 19. Ex. 35 at Figure 4. The ElAttrache '281 Patent also shows a proximally facing surface on the suture eyelet. See Appendices 6-8. The same is true for the Bio-Tenodesis Screw itself. See Appendices 6-8. For the same reasons mentioned above, it would have been obvious to combine these references showing this feature with the prior art references mentioned above for claim 1 and arrive at the limitations of this claim.

5. Claim 5 of the '942 Patent

a. Anticipation

The ElAttrache/Arthrex Work includes every limitation of claim 5 of the ‘942 Patent.

Claim 5 depends from claim 4 and includes a second distally facing surface on the proximal member facing toward the first surface. This is shown by the distally facing surface at the front end of the anchor body for the Bio-Tenodesis screw. See Appendices 5-6.

b. Obviousness

It would have been obvious, in view of the above-identified prior art references, to combine different features of those references and arrive at the limitations of this claim. For example, the Greenfield ‘835 Patent shows a distally facing surface on the anchor cap. Supra at 21-23. The Burkhart ‘272 Patent shows an anchor body with a distally facing surface. See Appendices 6-8. The ElAttrache ‘281 Patent also shows a distally facing surface on the anchor body. See Appendices 6-8. The same is true for the Bio-Tenodesis Screw itself. See Appendices 6-8. For the same reasons mentioned above, it would have been obvious to combine these references showing this feature with the prior art references mentioned above for claim 4 and arrive at the limitations of this claim.

6. Claim 6 of the ‘942 Patent

a. Anticipation

The ElAttrache/Arthrex Work includes every limitation of claim 6 of the ‘942 Patent. Claim 6 depends from claim 5 and requires that the proximal member be configured to move relative to the distal member so that the first and second surfaces can be positioned either spaced apart from one another or in close proximity with each other. This is shown by the anchor body (screw) of the Bio-Tenodesis Screw being inserted into the bone hole while the suture eyelet is at the bottom of the bone hole. Supra at 9-16.

b. Obviousness

It would have been obvious, in view of the above-identified prior art references, to combine different features of those references and arrive at the limitations of this claim. For example, the Greenfield '835 Patent shows an anchor cap able to move relative to the anchor base. The Burkhart '272 Patent shows an anchor body being inserted into the bone hole while the eyelet is at the bottom of the bone hole. Supra at 26-28. The ElAttrache '281 Patent also shows a screw anchor body being inserted into the bone hole with the suture eyelet at the bottom of the bone hole. Supra at 28-30. The same is true for the Bio-Tenodesis Screw itself. See Appendices 6-8. For the same reasons mentioned above, it would have been obvious to combine these references showing this feature with the prior art references mentioned above for claim 5 and arrive at the limitations of this claim.

7. Claim 7 of the '942 Patent

a. Anticipation

The ElAttrache/Arthrex Work includes every limitation of claim 7 of the '942 Patent. Claim 7 depends from claim 1 and requires that the distal member of the second anchor be tapered. This is shown by tapering of the suture eyelet at the end of the driver for the Bio-Tenodesis screw. See Appendices 5-6.

b. Obviousness

It would have been obvious, in view of the above-identified prior art references, to combine different features of those references and arrive at the limitations of this claim. For example, the Greenfield '835 Patent shows the bottom of the anchor base is tapered. Supra at 21-23. The ElAttrache '281 Patent shows a tapered suture eyelet at the end of the driver. Supra at 28-30. The same is true for the Bio-Tenodesis Screw itself. See Appendices 6-8. The Millett work also shows a tapered distal member of the second anchor. See Appendices 6-8. It would

have been obvious to combine these references showing this feature with the prior art references mentioned above for claim 1 because a person of ordinary skill would immediately realize the tapered distal member would facilitate anchor insertion.

8. Claim 9 of the '942 Patent

Claim 9 depends from claim 1 and requires that a proximal end of the distal member of the second anchor have a hole opening into a central bore. It would have been obvious, in view of the above-identified prior art references, to combine different features of those references and arrive at the limitations of this claim. For example, the Greenfield '835 Patent shows the base portion of the anchor having a hole opening into a central bore. Supra at 21-23. In addition, U.S. Patent No. 5,084,050 to Draenert ("the Draenert '050 Patent") (Ex. 41) shows that implant 10/10A are each a "hollow cylinder" having a hole opening into a central bore. See, e.g., Ex. 41 at Figures 1 and 3. See also Appendices 6-8. For the same reasons mentioned above, it would have been obvious to combine these references showing this feature with the prior art references mentioned above for claim 1 and arrive at the limitations of this claim.

9. Claim 10 of the '942 Patent

Claim 10 depends from claim 9 and requires the sides of the central bore to have threads. It would have been obvious, in view of the above-identified prior art references, to combine different features of those references and arrive at the limitations of this claim. For example, the central bore shown in the Greenfield '835 Patent has threads. Ex. 29 at column 8, lines 51-56. For the same reasons mentioned above, it would have been obvious to combine these references showing this feature with the prior art references mentioned above for claim 9 and arrive at the limitations of this claim.

10. Claim 11 of the '942 Patent

a. Anticipation

The ElAttrache/Arthrex Work includes every limitation of claim 11 of the '942 Patent.

Claim 11 depends from claim 1 and requires that the proximal member of the second anchor be cylindrically shaped. This is shown by the cylindrical shape of the anchor body (screw) of the Bio-Tenodesis screw. Supra at 9-16.

b. Obviousness

It would have been obvious, in view of the above-identified prior art references, to combine different features of those references and arrive at the limitations of this claim. For example, the ElAttrache '281 Patent shows an anchor body having a cylindrical shape. The Burkhardt '272 Patent also shows an anchor body with a cylindrical shape. Supra at 26-28. The same is true for the Bio-Tenodesis Screw itself. See Appendices 6-8. For the same reasons mentioned above, it would have been obvious to combine these references showing this feature with the prior art references mentioned above for claim 1 and arrive at the limitations of this claim. A person of ordinary skill in the art would also immediately know that most suture anchors are cylindrically shaped to provide structural strength and ease of insertion into bone either by screwing or impacting.

11. Claim 12 of the '942 Patent

a. Anticipation

The ElAttrache/Arthrex Work includes every limitation of claim 12 of the '942 Patent.

Claim 12 depends from claim 1 and requires that a central bore extend through the proximal member of the second anchor. This is shown by the hollow center of the anchor body (screw) of the Bio-Tenodesis screw. Supra at 9-16.

b. Obviousness

It would have been obvious, in view of the above-identified prior art references, to combine different features of those references and arrive at the limitations of this claim. For example, the ElAttrache '281 Patent shows an anchor body having a hollow center. The Burkhardt '272 Patent also shows an anchor body with a hollow center. Supra at 26-28. The same is true for the Bio-Tenodesis Screw itself. See Appendices 6-8. For the same reasons mentioned above, it would have been obvious to combine these references showing this feature with the prior art references mentioned above for claim 1 and arrive at the limitations of this claim. A person of ordinary skill would also realize that if the proximal member of the anchor has a central bore, the anchor can be mounted on an inserter passing through the anchor center which would facilitate anchor insertion into bone.

12. Claim 13 of the '942 Patent

a. Anticipation

The ElAttrache/Arthrex Work includes every limitation of claim 13 of the '942 Patent. Claim 13 depends from claim 12 and requires that the step of inserting the distal member of the second anchor and moving the proximal member of the second anchor distally toward the distal member includes using an anchor inserter having a handle, a tube and an inner member, where the inner member extends through the tube and central bore in the proximal member of the second anchor and is removably coupled to the distal member of the second anchor. This is shown by the handle, tube and inner member on the inserter of the Bio-Tenodesis screw used in the ElAttrache/Arthrex Work. The inner member extends through the anchor body and is removably coupled to the suture eyelet (the distal member). See Appendices 5-6.

b. Obviousness

It would have been obvious, in view of the above-identified prior art references, to combine different features of those references and arrive at the limitations of this claim. For example, the ElAttrache '281 Patent shows an anchor inserter (driver 30) having a handle (32, Figure 7), a tube (outer shaft 36, Figure 7), and an inner member (inner shaft 34, figure 7), where the inner member extends through the tube (Ex. 36 at column 3, lines 52-54) and the central bore in the proximal member of the second anchor (Ex. 36 at column 3, lines 40-42) and is removably coupled to the distal member (suture loop 70) of the second anchor. See Appendices 6-8. This is also shown in the Bio-Tenodesis Screw itself. See Appendices 6-8. The Burkhart '272 Patent also shows an anchor inserter (driver 100) comprising a handle (15), a tube (outer shaft 19), and an inner member (inner shaft 19), wherein the inner member extends through the tube (Ex. 35 at column 3, lines 36-37 ("The outer shaft 17 is cannulated for receiving inner shaft 19.")) and the central bore in the proximal member of the second anchor (Ex. 35 at column 3, lines 45-48 ("The cannulation formed through the screw is preferably hex-shaped and accepts the correspondingly shaped inner shaft 19 of driver 100.")) and is removably coupled to the distal member of the second anchor (e.g., figure 7)). See Appendices 6-8. For the same reasons mentioned above, it would have been obvious to combine these references showing this feature with the prior art references mentioned above for claim 12 and arrive at the limitations of this claim. A person of ordinary skill would also realize that these features would facilitate insertion of the anchor into bone.

13. Claim 14 of the '942 Patent

a. Anticipation

The ElAttrache/Arthrex Work includes every limitation of claim 14 of the '942 Patent. Claim 14 depends from claim 13 and requires that the inserter have an inner tube and an outer

tube where the inner tube extends through the outer tube and where the inner member extends through the inner tube. These features are shown on the inserter of the Bio-Tenodesis screw used in the ElAttrache/Arthrex Work. See Appendices 5-6.

b. Obviousness

It would have been obvious, in view of the above-identified prior art references, to combine different features of those references and arrive at the limitations of this claim. For example, these same features are also shown on the inserter of the Bio-Tenodesis screw itself. See Appendices 6-8. The ElAttrache '281 Patent shows the inserter 30 having an inner tube 37 or tapered section 37' (e.g., Ex. 36 at Figures 9 and 11) and an outer tube 40 (e.g., Figure 7), where the inner tube extends through the outer tube (consistent with KFx's infringement contentions), and where the inner member extends through the inner tube. See Appendices 6-8. For the same reasons mentioned above, it would have been obvious to combine these references showing this feature with the prior art references mentioned above for claim 13 and arrive at the limitations of this claim. A person of ordinary skill would also realize that these features would facilitate insertion of the anchor into bone.

14. Claim 15 of the '942 Patent

a. Anticipation

The ElAttrache/Arthrex Work includes every limitation of claim 15 of the '942 Patent. Claim 15 depends from claim 13 and requires that the tube is moveable longitudinally relative to the inner member. This is shown on the inserter for the Bio-Tenodesis screw used in the ElAttrache/Arthrex Work. Supra at 9-16. See also Appendices 5-6.

b. Obviousness

It would have been obvious, in view of the above-identified prior art references, to combine different features of those references and arrive at the limitations of this claim. For example, this feature is also shown on the inserter of the Bio-Tenodesis screw itself. See Appendices 6-8. The ElAttrache '281 Patent also shows this feature. See Ex. 36 at column 3, lines 52-54 ("Outer shaft 36 includes a sleeve 40 which covers and is slidable over shaft body 38"). The Burkhart '272 Patent also shows this feature. See Ex. 35 at Figures 5-7 and accompanying text. For the same reasons mentioned above, it would have been obvious to combine these references showing this feature with the prior art references mentioned above for claim 13 and arrive at the limitations of this claim. A person of ordinary skill would also realize that these features would facilitate insertion of the anchor into bone.

15. Claim 16 of the '942 Patent

a. Anticipation

The ElAttrache/Arthrex Work includes every limitation of claim 16 of the '942 Patent. Claim 16 depends from claim 1 and requires coupling the first length of suture to the second anchor prior to inserting the distal member of the second anchor into bone. This is shown in the ElAttrache/Arthrex Work where the suture attached to the medial anchor is threaded through the suture eyelet of the Bio-Tenodesis screw prior to the eyelet being positioned at the bottom of the bone hole. Supra at 9-16.

b. Obviousness

It would have been obvious, in view of the above-identified prior art references, to combine different features of those references and arrive at the limitations of this claim. For example, this feature is also shown in use of the Bio-Tenodesis screw itself. See Appendices 6-8. The ElAttrache '281 Patent also shows this feature with a suture threaded through the suture

eyelet prior to placing the suture eyelet inside the bone hole. Supra at 28-30. And the Burkhardt '272 Patent also shows this feature with a suture threaded through the plastic eyelet prior to placing the eyelet inside the bone hole. Supra at 26-28. For the same reasons mentioned above, it would have been obvious to combine these references showing this feature with the prior art references mentioned above for claim 1 and arrive at the limitations of this claim.

c. Lack of Written Description, Enablement and Best Mode

I do not believe the specification of the KFx Patents includes a sufficient written description to enable a person of ordinary skill in the art to make and use a second anchor in which suture is coupled to the second anchor prior to inserting the distal member of the second anchor into bone. The only description of a second anchor in the specification is the two-piece second anchor. There is no description about how the suture would be coupled to the two-piece second anchor prior to the anchor being inserted into the bone. I cannot visualize how the suture would be coupled to the two-piece anchor prior to being inserted into bone because the only time the suture is touching the second anchor is when it is being tensioned and then captured between the two anchor portions, and both occur only after the second anchor has already been inserted. Since there is no description of how to achieve this, there is also no description of what the inventors believed to be their best mode for achieving it.

16. Claim 17 of the '942 Patent

a. Anticipation

The ElAttrache/Arthrex Work includes every limitation of claim 17 of the '942 Patent. Claim 17 depends from claim 1 and requires that tensioning comprises manually pulling on the first length of suture. This is shown in the ElAttrache/Arthrex Work where the suture eyelet is

placed at the bottom of the bone hole and the suture threaded through the eyelet is tensioned by hand. Supra at 9-16.

b. Obviousness

It would have been obvious, in view of the above-identified prior art references, to combine different features of those references and arrive at the limitations of this claim. For example, this feature is also shown in the instructions for using the Bio-Tenodesis screw itself. See Appendices 6-8. The ElAttrache '281 Patent also shows manually tensioning the suture threaded through the suture eyelet. See Ex. 36 at column 5, lines 25-26. The Greenfield '835 Patent also shows manually tensioning the suture threaded through the anchor cap. See Ex. 29 at column 9, lines 35-39 ("Once engaged, the surgeon can pull on the suture material while it is threaded through the suture anchor and apply a proper tension to the suture to adjust the position of the soft tissue (not shown) and the tension of the suture thereon"). For the same reasons mentioned above, it would have been obvious to combine these references showing this feature with the prior art references mentioned above for claim 1 and arrive at the limitations of this claim. A person of ordinary skill would also immediately realize that tensioning is best achieved manually during surgery since manually tensioning provides feedback which allows the surgeons to judge when tension is sufficient without the need for other instruments or gauges.

17. Claim 18 of the '942 Patent

a. Anticipation

The ElAttrache/Arthrex Work includes every limitation of claim 18 of the '942 Patent. Claim 18 depends from claim 1 and includes inserting a third anchor into bone underneath the soft tissue, passing a second length of suture from the third anchor over the soft tissue, tensioning the second length of suture independently from the first length of suture, and after tensioning the

first and second lengths of suture, moving the proximal member of the second anchor distally toward the distal member of the second anchor, thereby fixedly securing the first and second lengths of suture at the second anchor position without tying any knots. These steps are shown in the ElAttrache/Arthrex Work, for example, when a second medial anchor is inserted underneath the soft tissue and the suture attached to that second medial anchor is threaded through the same suture loop as the suture from the first medial anchor. Both suture lengths are independently tensioned and then the anchor body is screwed into the bone hole to wedge the sutures between the anchor body and the bone hole. Supra at 9-16. This is also shown in the ElAttrache/Arthrex Work describing a linked double row construct with suture from two medial anchors being connected in a knotless fashion to two lateral anchors in a criss-cross pattern. Supra at 9-16.

b. Obviousness

It would have been obvious, in view of the above-identified prior art references, to combine different features of those references and arrive at the limitations of this claim. For example, the Millett work shows a second medial anchor being inserted into bone underneath the soft tissue and the suture attached to the second medial anchor being passed over the soft tissue. Supra at 16-20. The Millett work also shows the two strands of suture being tensioned independently as they are two separate strands of suture. Supra at 16-20. This would also have been obvious to a person of ordinary skill in the 2004 timeframe since it is easier to tension one suture strand at a time when two strands are threaded through the eyelet and located at the bottom of the bone hole with limited space available to movement. This would ensure that all slack is removed from both suture strands.

The ElAttrache '281 Patent shows moving the anchor body toward the suture eyelet to wedge the suture between the anchor body and the bone wall. This is also shown in the Burkhardt '272 Patent when the anchor body is inserted into the bone hole on top of the eyelet. Supra at 26-28. For the same reasons mentioned above, it would have been obvious to combine these references showing this feature with the prior art references mentioned above for claim 1 and arrive at the limitations of this claim. It also would have been obvious to an orthopedic surgeon at the time to add anchors and suture strands to the construct to strengthen the repair by adding compression over a larger footprint.

18. Claim 19 of the '942 Patent

a. Anticipation

The ElAttrache/Arthrex Work includes every limitation of claim 19 of the '942 Patent. It discloses a method of attaching soft tissue to bone. Supra at 9-16. It also shows the insertion of a first anchor by, for example, the insertion of the Corkscrew anchor underneath the simulated tissue. Supra at 9-16. The ElAttrache/Arthrex Work also shows passing a first length of suture from the first anchor over the soft tissue, for example, when the suture is passed through the tissue to the top side of the tissue. Supra at 9-16. The ElAttrache/Arthrex Work further shows coupling the first length of suture to the second anchor, for example, when the suture is threaded through the suture eyelet at the end of the Bio-Tenodesis driver. Supra at 9-16. It also shows a second anchor with a distal and proximal member where the proximal member is cylindrical and has a central bore extending through it. This is shown by the suture eyelet (distal member) and the anchor body (proximal member) and the hollow, cylindrical anchor body. Supra at 9-16. The ElAttrache/Arthrex Work also shows inserting the distal member of the second anchor when the suture eyelet is placed at the bottom of the bone hole. Supra at 9-16. It also shows

tensioning the suture to compress the tissue between the edge of the soft tissue and the first anchor. Supra at 9-16. The ElAttrache/Arthrex Work also shows the anchor body moving toward the suture eyelet in order to wedge the suture between the anchor body and the bone wall without tying any knots. Supra at 9-16. And it also shows the claimed features of the inserter for the second anchor. See Appendices 6-8.

b. Obviousness

It would have been obvious, in view of the above-identified prior art references, to combine different features of those references and arrive at the limitations of this claim. For example, the Millett work, the Thal '168 Patent, the Burkhart '272 Patent, the ElAttrache '281 Patent, the Guanche work, among other prior art references, describe a method of attaching soft tissue to bone. Supra at 16-20, 20-21, 26-28, 28-30, 24-26. The Millett work and Thal '168 also show the insertion of a first anchor underneath the tissue. Supra at 16-20, 20-21. Those same references, among others, also show passing a first length of suture from the first anchor over the soft tissue, for example, when the suture is passed through the tissue to the top side of the tissue. Supra at 16-20, 20-21.

Coupling the suture to the second anchor is shown, for example, in the Burkhart '272 Patent when the suture is threaded through the eyelet at the end of the driver. Supra at 26-28. The same is true for the ElAttrache '281 Patent which shows the suture being threaded through the suture eyelet at the end of the driver. Supra at 28-30. This is also shown in application of the Bio-Tenodesis screw itself. See Appendix 9-16. And for each of these references, the anchor is cylindrical and has a hollow center.

Inserting a distal member of a second anchor is shown, for example, in the Greenfield '835 Patent which shows the anchor base being screwed into bone. Supra at 21-23. The

Burkhart '272 Patent also discloses many features of the accused PushLock anchors, including a separate eyelet portion and anchor body. Supra at 26-28. These same features are shown in the ElAttrache '281 Patent, which discloses many of the features of the accused Bio-Tenodesis Screw, including a separate suture eyelet and anchor body. Supra at 28-30. These same features are also shown in the Bio-Tenodesis Screw itself, which is an accused product and prior art to the KFx patents. Supra at 9-16. Tensioning the suture is also shown in each of these same references. Supra at 9-16, 21-23, 26-28, 28-30.

The Greenfield '835 Patent shows the anchor cap moving toward the anchor base. Supra at 21-23. And the Burkhart '272 Patent, ElAttrache '281 Patent and the Bio-Tenodesis Screw show the anchor body moving toward the eyelet while the eyelet is at the bottom of the bone hole and the suture being wedged between the anchor body and the bone wall. Supra at 26-28, 28-30, 9-16. The claimed features of the inserter are shown in the driver of the Bio-Tenodesis screw. See Appendices 6-8. For the same reasons mentioned above, it would have been obvious to combine these references showing this feature with the prior art references mentioned above for claim 1 and arrive at the limitations of this claim.

c.       Lack of Written Description, Enablement and Best Mode

I do not believe the specification of the KFx Patents includes a sufficient written description to enable a person of ordinary skill in the art to make and use a second anchor in which suture is coupled to the second anchor prior to inserting the distal member of the second anchor into bone. The only description of a second anchor in the specification is the two-piece second anchor. There is no description about how the suture would be coupled to the two-piece second anchor prior to the anchor being inserted into the bone. I cannot visualize how the suture would be coupled to the two-piece anchor prior to being inserted into bone because the only time

the suture is touching the second anchor is when it is being tensioned and then captured between the two anchor portions, and both occur only after the second anchor has already been inserted. Since there is no description of how to achieve this, there is also no description of what the inventors believed to be their best mode for achieving it.

H. The '969 Patent

Based on my review of the prior art and the asserted claims of the '969 Patent, as interpreted by the Court, it is my opinion that the ElAttrache/Arthrex Work anticipates asserted claims 1-7 and 14-17 because it includes every limitation of each of those claims. To the extent that the ElAttrache/Arthrex Work does not anticipate any of the asserted claims, it would have been obvious to add any of the references discussed above or in the Appendices to the ElAttrache/Arthrex Work for the reasons stated below.

It is also my opinion that each of the asserted claims of the '969 Patent is invalid because it would have been obvious to a person of ordinary skill in the art in the 2004-2005 timeframe to combine various features of: i) the ElAttrache/Arthrex Work, ii) the Thal '904 Publication, iii) the Millet work, iv) the Thal '168 Patent, v) the ElAttrache '281 Patent, vi) the Burkhardt '272 Patent, vii) the Greenfield '835 Patent, viii) the Guanche Work and other prior art references identified in the claim charts, and arrive at the limitations of the asserted claims.

It is further my opinion that each asserted claim of the '969 Patent is invalid because they are not supported by a sufficient written description that would enable a person of ordinary skill in the art to make and use the invention and also because the inventors did not describe their best mode.

Exemplary bases for my opinions are included below for each asserted claim of the '969 Patent. More complete and additional bases supporting my opinions are included in the claim charts attached to my report at Appendices 9-13.

1. Claim 1 of the '969 Patent

a. Anticipation

The ElAttrache/Arthrex Work includes every limitation of claim 1 of the '969 Patent. It discloses a method of attaching soft tissue to bone. Supra at 9-16. It also shows the insertion of a first anchor by, for example, the insertion of the Corkscrew anchor underneath the simulated tissue. Supra at 9-16. The ElAttrache/Arthrex Work also shows passing a first length of suture from the first anchor over the soft tissue, for example, when the suture is passed through the tissue to the top side of the tissue. Supra at 9-16. The ElAttrache/Arthrex Work further shows inserting at least a portion of a second anchor into bone beyond an edge of the soft tissue where the suture eyelet of the Bio-Tenodesis Screw is placed into the bone hole. Supra at 9-16. The ElAttrache/Arthrex Work also shows after inserting the at least a portion of the second anchor tensioning the suture by tensioning the suture threaded through the suture eyelet with the suture eyelet at the bottom of the bone hole. Supra at 9-16. It also shows after tensioning fixedly securing the first length of suture at the second anchor position without tying any knots. Supra at 9-16. And the ElAttrache/Arthrex Work shows that the lateral Bio-Tenodesis screw has an anchor tip and a hollow cylinder (anchor body), where the anchor tip has an aperture (suture eyelet) through which suture material is threaded before inserting the Bio-Tenodesis anchor. Supra at 9-16.<sup>10</sup>

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<sup>10</sup> KFx's contentions are based on the eyelet of PushLock and SwiveLock as being the anchor tip having an aperture. I disagree that the eyelet on those products is an anchor tip. As described above, the eyelet is a separate piece from the anchor body and serves an entirely

b. Obviousness

It would have been obvious, in view of the above-identified prior art references, to combine different features of those references and arrive at the limitations of this claim. For example, the Millett work, the Thal '168 Patent, the Burkhart '272 Patent, the ElAttrache '281 Patent, the Guanche work, among other prior art references, describe a method of attaching soft tissue to bone. Supra at 16-20, 20-21, 26-28, 28-30, 24-26. The Millett work and Thal '168 also show the insertion of a first anchor underneath the simulated tissue. Supra at 16-20, 20-21. Those same references, among others, also show passing a first length of suture from the first anchor over the soft tissue, for example, when the suture is passed through the tissue to the top side of the tissue. Supra at 16-20, 20-21.

Inserting at least a portion of a second anchor is shown, for example, in the Greenfield '835 Patent which shows the anchor base being screwed into the bone. Supra at 21-23. This is also shown in the Burkhart '272 Patent, which discloses many features of the accused PushLock anchors, including a separate eyelet portion and anchor body. Supra at 26-28. These same features are shown in the ElAttrache '281 Patent, which discloses many of the features of the accused Bio-Tenodesis Screw, including a separate suture eyelet and anchor body. Supra at 28-30. These same features are also shown in the Bio-Tenodesis Screw itself, which is an accused product and prior art to the KFx patents.

These same references also show that the suture is tensioned after the at least a portion of the second anchor is inserted into bone. For example, this is shown in the Greenfield '835 Patent when the anchor body is inserted into bone and the suture threaded through the cap is tensioned. Supra at 21-23. This is also shown in the Burkhart '272 Patent (supra at 26-28); the ElAttrache

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different purpose than the anchor. The eyelet does not anchor the suture in the bone hole. Rather, anchoring of the suture is done by the anchor body.

‘281 Patent (supra at 28-30); the Guanche work (supra at 24-26), among several other references described in the claim charts. And these same references show that after tensioning the suture the suture is fixedly secured at the second anchor position without tying any knots. This is shown, for example, in the Greenfield ‘835 Patent where the anchor cap is advanced into the anchor base to wedge the suture between the two anchor portions much in the same way as the second anchor described in the KFx Patents. Supra at 21-23. This is also shown in the Burkhardt ‘272 Patent (supra at 26-28); the ElAttrache ‘281 Patent (supra at 28-30) and the Guanche work (supra at 24-26), when the anchor body is screwed into the bone to wedge the suture between the anchor body and the bone wall.

These same references also show at least one anchor having an anchor tip and hollow cylinder, where the anchor tip has an aperture through which suture material is threaded prior to inserting the anchor. This is shown by suture eyelet of the Bio-Tenodesis anchor used in the ElAttrache/Arthrex Work (supra at 9-16), the Guanche Work (supra at 24-26), the ElAttrache ‘281 Patent (supra at 28-30) and the accused Bio-Tenodesis anchor itself (supra at 9-16). It is also shown by the plastic eyelet at the end of the driver in the Burkhardt ‘272 Patent. Supra at 26-30.

A person of ordinary skill in the art during the 2004 timeframe would have been motivated to combine these references and arrive at the claimed invention because all of the references are in the same field of orthopedic surgery. The examiner already combined two such prior art references (the ‘Thal 168 Patent and the Jobe ‘926 Patent) in rejecting the claims.

A person of ordinary skill in the art also would have understood that an obvious result of combining these references would create a better surgical process due to the increased flexibility by allowing a portion of the anchor to be inserted into the bone and then tensioning the suture

before the suture is fixedly secured to the anchor. This eliminates the need for deciding ahead of time how much tension should be in the suture.

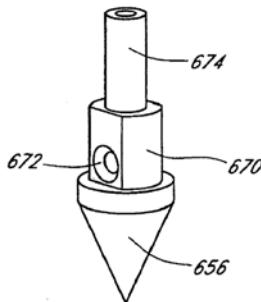
A person of ordinary skill in the art would also have known that an obvious way to facilitate tensioning of the suture after the portion of the second anchor is inserted into bone is to have first threaded the suture through an aperture at the second anchor tip so that the suture could be located at the bottom of the hole. And it would have been obvious that the hollow cylindrical shape of the anchor would facilitate anchor insertion by allowing the anchor to be mounted on a driver.

c. Lack of Written Description, Enablement and Best Mode

I understand the way KFx is asserting this claim against Arthrex's PushLock anchors, which are the lateral (second) anchors in the accused SutureBridge method, the anchor tip with an aperture refers to the eyelet at the end of the driver. However, I do not believe the specification of the KFx Patents includes a sufficient written description to enable a person of ordinary skill in the art to make and use a second anchor having a tip with an aperture through which suture is threaded before the anchor is inserted into the bone; the way KFx is applying this claim term against PushLock.

The only description of a second anchor in the specification is the two-piece second anchor. The two-piece second anchor does not have an aperture nor is there any description about how the suture would be threaded through any such aperture on the second anchor prior to inserting the second anchor. I cannot visualize how the suture would be threaded through an aperture on the two-piece anchor prior to being inserted into bone because the only time the suture is described as touching the second anchor is when it is being tensioned and then captured between the two anchor portions, and both occur only after the second anchor has already been

inserted. Further, the only anchor described in the specification as having an anchor tip with an aperture through which suture is threaded prior to insertion is the first (medial) anchor. These features are shown below in Figure 11 of the '969 Patent, which is a piercing bone anchor tip 656 with an aperture 672.



**FIG. 11**

Further, since there is no description of a second anchor having these features and no description of how suture would be threaded through an aperture on the second anchor, if the inventors had a best mode for doing so, it is not described in the specification.

2. Claim 2 of the '969 Patent

a. Anticipation

The ElAttrache/Arthrex Work includes every limitation of claim 2 of the '969 Patent. Claim 2 depends from claim 1 and requires the anchor tip to have an engaging member adapted to engage an inner surface of the cylinder. Assuming KFx is correct and the eyelet is the anchor tip, then the outer surface of the suture eyelet used with the Bio-Tenodesis screw is the engaging member which is adapted to engage an inner surface of the anchor body. See Appendices 9-10.

b. Obviousness

It would have been obvious, in view of the above-identified prior art references, to combine different features of those references and arrive at the limitations of this claim. For

example, the Burkhart '272 Patent shows an anchor tip (eyelet implant 50) having an engaging member (outer surface of eyelet implant 50) adapted to engage (column 4, line 46) an inner surface of the anchor body 20. See Appendices 10-13. For the same reasons mentioned above, it would have been obvious to combine this reference showing this feature with the prior art references mentioned above for claim 1 and arrive at the limitations of this claim.

3. Claim 3 of the '969 Patent

a. Anticipation

The ElAttrache/Arthrex Work includes every limitation of claim 3 of the '969 Patent. Claim 3 depends from claim 1 and requires the anchor tip to have an anchor inserter attachment member. Assuming KFx is correct and the eyelet is the anchor tip, then this is shown by the portion of the suture eyelet that is touching the end of the anchor inserter. See Appendices 9-10.

b. Obviousness

It would have been obvious, in view of the above-identified prior art references, to combine different features of those references and arrive at the limitations of this claim. For example, the Burkhart '272 Patent shows that the eyelet 50 is attached to the end 12 of the driver 100 by a connector 57 [anchor inserter attachment member]. See e.g., Ex. 35 at column 3, lines 56-58. See also Appendices 10-13. For the same reasons mentioned above, it would have been obvious to combine this reference showing this feature with the prior art references mentioned above for claim 1 and arrive at the limitations of this claim.

4. Claim 4 of the '969 Patent

a. Anticipation

The ElAttrache/Arthrex Work includes every limitation of claim 4 of the '969 Patent. Claim 4 depends from claim 3 and requires an inserter having a handle, an outer sleeve, and an

inner member, where the inner member extends through the outer sleeve and the hollow cylinder and is attached to the anchor inserter attachment member. This is shown by the Bio-Tenodesis driver that includes a handle (e.g., the tear drop handle for the BioTenodesis driver), an outer sleeve, and an inner member (portion of suture extending through cannulated Bio Tenodesis driver), wherein the inner member (suture) extends through the outer sleeve and the hollow cylinder and is attached to the anchor inserter attachment member (the portion of the suture loop making contact with the tip of the driver). See Appendices 9-10.

b. Obviousness

It would have been obvious, in view of the above-identified prior art references, to combine different features of those references and arrive at the limitations of this claim. For example, the Burkhart '272 Patent shows an inserter with a handle (15), an outer sleeve (outer shaft 17), and an inner member (inner shaft 19), where the inner member extends through the outer sleeve (outer shaft 17) and the hollow cylinder (interference device 20) and is attached to the anchor inserter attachment member (connector 57, e.g., column 3, lines 56-58). For the same reasons mentioned above, it would have been obvious to combine this reference showing this feature with the prior art references mentioned above for claim 3 and arrive at the limitations of this claim.

5. Claim 5 of the '969 Patent

a. Anticipation

The ElAttrache/Arthrex Work includes every limitation of claim 5 of the '969 Patent. Claim 5 depends from claim 4 and requires that the inserter have an inner tube extending through the outer sleeve and through the hollow cylinder and contacts the anchor tip, where the inner member extends through the inner tube. This is shown by the Bio-Tenodesis driver having an

inner tube extending through the outer sleeve and through the hollow cylinder (screw) and contacts the anchor tip (loop/snare of FiberStick Snare), where the inner member (suture extending through cannulation in inner tube) extends through the inner tube. See Appendices 9-10.

b. Obviousness

It would have been obvious, in view of the above-identified prior art references, to combine different features of those references and arrive at the limitations of this claim. For example, the ElAttrache '281 Patent shows that the inserter has an inner tube (inner shaft 34) extending through the outer sleeve (outer shaft 36) and through the hollow cylinder (screw 10) and contacts the anchor tip (suture loop 70), where the inner member (traction suture 68) extends through the inner tube (inner shaft 34). See Ex. 36 at Figures 7-10 and 15. See Appendices 10-13. For the same reasons mentioned above, it would have been obvious to combine these references showing this feature with the prior art references mentioned above for claim 4 and arrive at the limitations of this claim.

6. Claim 6 of the '969 Patent

a. Anticipation

The ElAttrache/Arthrex Work includes every limitation of claim 6 of the '969 Patent. Claim 6 depends from claim 5 and requires that the inner tube be fixed relative to the handle. This is shown by the Bio-Tenodesis driver having a handle and an inner tube that are fixed relative to one another. See Appendices 9-10.

b. Obviousness

It would have been obvious, in view of the above-identified prior art references, to combine different features of those references and arrive at the limitations of this claim. For example, the ElAttrache '281 Patent shows that the inserter has an inner tube (inner shaft 34) that is fixed relative to the handle. See, e.g., Ex. 36 at column 5, lines 29-32 describing how inner shaft rotates as handle is rotated. See Appendices 10-13. For the same reasons mentioned above, it would have been obvious to combine these references showing this feature with the prior art references mentioned above for claim 5 and arrive at the limitations of this claim.

7. Claim 7 of the '969 Patent

a. Anticipation

The ElAttrache/Arthrex Work includes every limitation of claim 7 of the '969 Patent. Claim 7 depends from claim 5 and requires that the inner tube be moveable axially relative to the outer sleeve. This is shown by the Bio-Tenodesis driver having an inner tube that is moveable axially relative to the outer sleeve. See Appendices 9-10.

b. Obviousness

It would have been obvious, in view of the above-identified prior art references, to combine different features of those references and arrive at the limitations of this claim. For example, the ElAttrache '281 Patent shows that the outer shaft 36 moves distally along the inner shaft. See, e.g., Ex. 36 at column 5, lines 29-35. See Appendices 10-13. For the same reasons mentioned above, it would have been obvious to combine these references showing this feature with the prior art references mentioned above for claim 4 and arrive at the limitations of this claim.

8. Claim 13 of the '969 Patent

Claim 13 depends from claim 4 and adds that inserting the at least one anchor having an anchor tip and hollow cylinder includes tapping on the inserter with a hammer. It would have been obvious, in view of the above-identified prior art references, to combine different features of those references and arrive at the limitations of this claim. For example, the Burkhart '272 Patent describes that the plug is advanced into the pilot hole by tapping it into the bone. Ex. 35 at the Abstract. See Appendices 10-13. For the same reasons mentioned above, it would have been obvious to combine these references showing this feature with the prior art references mentioned above for claim 4 and arrive at the limitations of this claim.

9. Claim 14 of the '969 Patent

a. Anticipation

The ElAttrache/Arthrex Work includes every limitation of claim 14 of the '969 Patent. Claim 14 depends from claim 1 and requires coupling the first length of suture to the at least one anchor with an anchor tip and hollow cylinder prior to inserting the at least one anchor. This is shown when the suture from the medial anchor is threaded through the suture eyelet of the Bio-Tenodesis screw prior to the eyelet (or the anchor) being inserted into the bone hole. Supra at 9-16.

b. Obviousness

It would have been obvious, in view of the above-identified prior art references, to combine different features of those references and arrive at the limitations of this claim. For example, the Burkhart '272 Patent shows sutures being passed through the eyelet at the end of a driver prior to the eyelet being placed into the bone hole. See Ex. 35 at Figure 4 and column 4, lines 31-50. See Appendices 10-13. The ElAttrache '281 Patent also shows a strand of suture being threaded through the suture eyelet before the suture eyelet is placed at the bottom of the

bone hole. For the same reasons mentioned above, it would have been obvious to combine these references showing this feature with the prior art references mentioned above for claim 1 and arrive at the limitations of this claim.

c. Lack of Written Description, Enablement and Best Mode

I understand the way KFx is asserting this claim against Arthrex's PushLock anchors, which are the lateral (second) anchors in the accused SutureBridge method, the anchor tip with an aperture refers to the eyelet at the end of the driver. However, I do not believe the specification of the KFx Patents includes a sufficient written description to enable a person of ordinary skill in the art to make and use a second anchor having a tip with an aperture through which suture is threaded before the anchor is inserted into the bone; the way KFx is applying this claim term against PushLock.

The only description of a second anchor in the specification is the two-piece second anchor. The two-piece second anchor does not have an aperture nor is there any description about how the suture would be threaded through any such aperture on the second anchor prior to inserting the second anchor. I cannot visualize how the suture would be threaded through an aperture on the two-piece anchor prior to being inserted into bone because the only time the suture is described as touching the second anchor is when it is being tensioned and then captured between the two anchor portions, and both occur only after the second anchor has already been inserted. Further, the only anchor described in the specification as having an anchor tip with an aperture through which suture is threaded prior to insertion is the first (medial) anchor. These features are shown in Figure 11 of the '969 Patent, which is a piercing bone anchor tip 656 with an aperture 672. Since there is no description of a second anchor having these features and no

description of how suture would be threaded through an aperture on the second anchor, if the inventors had a best mode for doing so, it is not described in the specification.

10. Claim 15 of the '969 Patent

a. Anticipation

The ElAttrache/Arthrex Work includes every limitation of claim 15 of the '969 Patent. Claim 15 depends from claim 1 and requires that tensioning comprises manually pulling on the first length of suture. This is shown in the ElAttrache/Arthrex Work where the suture eyelet is placed at the bottom of the bone hole and the suture threaded through the eyelet is tensioned by hand. *Supra* at 9-16.

b. Obviousness

It would have been obvious, in view of the above-identified prior art references, to combine different features of those references and arrive at the limitations of this claim. For example, this feature is also shown in the instructions for using the Bio-Tenodesis screw itself. See Appendices 10-13. The ElAttrache '281 Patent also shows manually tensioning the suture threaded through the suture eyelet. See Ex. 36 at column 5, lines 25-26. The Greenfield '835 Patent also shows manually tensioning the suture threaded through the anchor cap. See Ex. 29 at column 9, lines 35-39 ("Once engaged, the surgeon can pull on the suture material while it is threaded through the suture anchor and apply a proper tension to the suture to adjust the position of the soft tissue (not shown) and the tension of the suture thereon"). For the same reasons mentioned above, it would have been obvious to combine these references showing this feature with the prior art references mentioned above for claim 1 and arrive at the limitations of this claim. A person of ordinary skill would also immediately realize that tensioning is best

achieved manually during surgery since manually tensioning provides feedback and allows the surgeon to judge when tension is sufficient without the need for other instruments or gauges.

11. Claim 16 of the '969 Patent

a. Anticipation

The ElAttrache/Arthrex Work includes every limitation of claim 16 of the '969 Patent. Claim 16 depends from claim 1 and includes inserting a third anchor into bone underneath the soft tissue, passing a second length of suture from the third anchor over the soft tissue, tensioning the second length of suture independently from the first length of suture, and after tensioning the first and second lengths of suture, fixedly securing both the first and second lengths of suture at the second anchor position without tying any knots. These steps are shown in the ElAttrache/Arthrex Work, for example, when a second medial anchor is inserted underneath the soft tissue and the suture attached to that second medial anchor is threaded through the same suture loop as the suture from the first medial anchor. Both suture lengths are independently tensioned and then the anchor body is screwed into the bone hole to wedge the sutures between the anchor body and the bone hole. Supra at 9-16. This is also shown in the ElAttrache/Arthrex Work describing a linked double row construct with suture from two medial anchors being connected in a knotless fashion to two lateral anchors in a criss-cross pattern. Supra at 9-16.

b. Obviousness

It would have been obvious, in view of the above-identified prior art references, to combine different features of those references and arrive at the limitations of this claim. For example, the Millett work shows a second medial anchor being inserted into bone underneath the soft tissue and the suture attached to the second medial anchor being passed over the soft tissue. Supra at 16-20. The Millett work also shows the two strands of suture being tensioned

independently as they are two separate strands of suture. Supra at 16-20. This would also have been obvious to a person of ordinary skill in the 2004 timeframe since it is easier to tension one suture strand at a time when two strands are threaded through the eyelet and located at the bottom of the bone hole with limited space available to movement. This would ensure that all slack is removed from both suture strands.

The ElAttrache '281 Patent shows fixedly securing the two strands of suture to the lateral anchor by wedging the sutures between the anchor body and the bone wall. Supra at 28-30. The Burkhardt '272 Patents shows the same thing. Supra at 26-28. For the same reasons mentioned above, it would have been obvious to combine these references showing this feature with the prior art references mentioned above for claim 1 and arrive at the limitations of this claim. It also would have been obvious to an orthopedic surgeon at the time to add anchors and suture strands to the construct to strengthen the repair by adding compression over a larger footprint.

12. Claim 17 of the '969 Patent

a. Anticipation

The ElAttrache/Arthrex Work includes every limitation of claim 17 of the '969 Patent. It discloses a method of attaching soft tissue to bone. Supra at 9-16. It also shows the insertion of a first anchor by, for example, the insertion of the Corkscrew anchor underneath the simulated tissue. Supra at 9-16. The ElAttrache/Arthrex Work also shows passing a first length of suture from the first anchor over the soft tissue, for example, when the suture is passed through the tissue to the top side of the tissue. Supra at 9-16. The ElAttrache/Arthrex Work further shows inserting at least a portion of a second anchor, for example, when the suture eyelet at the end of the Bio-Tenodesis driver is placed into the bone hole. Supra at 9-16. It also shows after inserting the at least a portion of a second anchor, tensioning the first length of suture to

compress the tissue to bone between the edge of the soft tissue and the first anchor, for example, when the suture from the medial anchor is tensioned with the suture eyelet at the bottom of the bone hole. Supra at 9-16.

The ElAttrache/Arthrex Works also shows after tensioning, fixedly securing the first length of suture at the second anchor position without tying any knots, for example, when the anchor body is screwed into the bone hole and wedges the suture between the anchor body and the bone wall. Supra at 9-16. It also shows at least one of the anchors has an anchor tip and a hollow cylinder, where the anchor tip has an aperture through which suture is threaded prior to inserting the at least one anchor. This is shown by the suture eyelet at the end of the driver through which suture from the medial anchor is threaded prior to placing the suture eyelet at the bottom of the bone hole. Supra at 9-16.

The Arthrex also show the anchor tip with an engaging member adapted to engage an inner surface of the cylinder, by for example, the outer surface of the suture eyelet used with the Bio-Tenodesis screw. See Appendices 9-10. It also shows an anchor inserter attachment member where the at least one anchor has an inserter with a handle, an outer sleeve, and an inner member, where the inner member extends through the outer sleeve and the hollow cylinder and is attached to the anchor inserter attachment member. This is shown by the Bio-Tenodesis driver that includes a handle (e.g., the tear drop handle for the BioTenodesis driver), an outer sleeve, and an inner member (portion of suture extending through cannulated Bio Tenodesis driver), wherein the inner member (suture) extends through the outer sleeve and the hollow cylinder and is attached to the anchor inserter attachment member (the portion of the suture loop making contact with the tip of the driver). See Appendices 9-10.

b. Obviousness

It would have been obvious, in view of the above-identified prior art references, to combine different features of those references and arrive at the limitations of this claim. For example, the Millett work, the Thal '168 Patent, the Burkhart '272 Patent, the ElAttrache '281 Patent, the Guanche work, among other prior art references, describe a method of attaching soft tissue to bone. Supra at 16-20, 20-21, 26-28, 28-30, 24-26. The Millett work and Thal '168 also show the insertion of a first anchor underneath the tissue. Supra at 16-20, 20-21. Those same references, among others, also show passing a first length of suture from the first anchor over the soft tissue, for example, when the suture is passed through the tissue to the top side of the tissue. Supra at 16-20, 20-21.

Inserting at least a portion of a second anchor is shown, for example, in the Greenfield '835 Patent, which shows the anchor base screwed into bone. Supra at 21-23. This is also shown in the Burkhart '272 Patent, which discloses many features of the accused PushLock anchors, including a separate eyelet portion and anchor body. Supra at 26-28. These same features are shown in the ElAttrache '281 Patent, which discloses many of the features of the accused Bio-Tenodesis Screw, including a separate suture eyelet and anchor body. Supra at 28-30. These same features are also shown in the Bio-Tenodesis Screw itself, which is an accused product and prior art to the KFx patents.

These same references also show that the suture is tensioned after the at least a portion of the second anchor is inserted into bone. For example, this is shown in the Greenfield '835 Patent (supra at 21-23); the Burkhart '272 Patent (supra at 26-28); the ElAttrache '281 Patent (supra at 28-30); the Guanche work (supra at 24-26), among other references described in the claim charts. And these same references show that after tensioning the suture the suture is fixedly secured at the second anchor position without tying any knots. This is shown in the Greenfield '835 Patent

when the anchor cap is advanced into the anchor base to capture the suture between the two anchor portions. Supra at 21-23. This is also shown in the Burkhart '272 Patent (supra at 26-28), the ElAttrache '281 Patent (supra at 28-30) and the Guanche work (supra at 24-26) when the anchor body is screwed into the bone to wedge the suture between the anchor body and the bone wall.

These same references also show at least one anchor having an anchor tip and hollow cylinder, where the anchor tip has an aperture through which suture material is threaded prior to inserting the anchor. This is shown by suture eyelet of the Bio-Tenodesis anchor used in the ElAttrache/Arthrex Work (supra at 9-16), the Guanche Work (supra at 24-26), the ElAttrache '281 Patent (supra at 28-30) and the accused Bio-Tenodesis anchor itself (supra at 9-16). It is also shown by the plastic eyelet at the end of the driver in the Burkhart '272 Patent. Supra at 26-28).

The Burkhart '272 Patent also shows an anchor tip (eyelet implant 50) having an engaging member (outer surface of eyelet implant 50) adapted to engage (Ex. 35 at column 4, line 46) an inner surface of the anchor body 20. See Appendices 10-13. That same reference shows that the eyelet 50 is attached to the end 12 of the driver 100 by a connector 57 [anchor inserter attachment member]. See e.g., Ex. 35 at column 3, lines 56-58. See also Appendices 10-13.

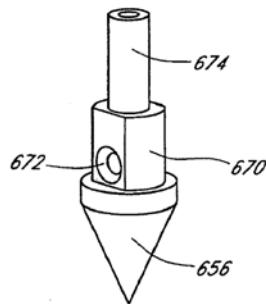
The Burkhart '272 Patent also shows an inserter with a handle (15), an outer sleeve (outer shaft 17), and an inner member (inner shaft 19), where the inner member extends through the outer sleeve (outer shaft 17) and the hollow cylinder (interference device 20) and is attached to the anchor inserter attachment member (connector 57, e.g., column 3, lines 56-58). For the same

reasons mentioned above, it would have been obvious to combine these references showing this feature with the prior art references mentioned above and arrive at the limitations of this claim.

c. Lack of Written Description, Enablement and Best Mode

I understand the way KFx is asserting this claim against Arthrex's PushLock anchors, which are the lateral (second) anchors in the accused SutureBridge method, the anchor tip with an aperture refers to the eyelet at the end of the driver. However, I do not believe the specification of the KFx Patents includes a sufficient written description to enable a person of ordinary skill in the art to make and use a second anchor having a tip with an aperture through which suture is threaded before the anchor is inserted into the bone; the way KFx is applying this claim term against PushLock.

The only description of a second anchor in the specification is the two-piece second anchor. The two-piece second anchor does not have an aperture nor is there any description about how the suture would be threaded through any such aperture on the second anchor prior to inserting the second anchor. I cannot visualize how the suture would be threaded through an aperture on the two-piece anchor prior to being inserted into bone because the only time the suture is described as touching the second anchor is when it is being tensioned and then captured between the two anchor portions, and both occur only after the second anchor has already been inserted. Further, the only anchor described in the specification has having an anchor tip with an aperture through which suture is threaded prior to insertion is the first (medial) anchor. These features are shown below in Figure 11 of the '969 Patent, which is a piercing bone anchor tip 656 with an aperture 672.



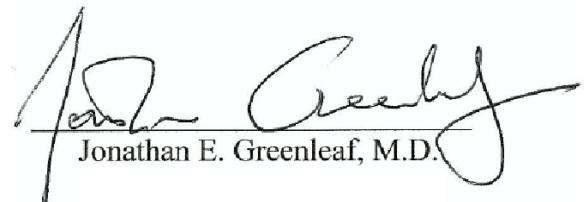
**FIG. 11**

Further, since there is no description of a second anchor having these features and no description of how suture would be threaded through an aperture on the second anchor, if the inventors had a best mode for doing so, it is not described in the specification.

**X. CONCLUSION**

The opinions expressed in this report are based on the information currently available to me. I specifically reserve the right to formulate additional opinions and supplement my opinions as additional information becomes known to me, and I likewise reserve the right to supplement my opinions based on future court rulings, agreements between the parties, additional evidence submitted by either party prior to or during trial, and any additional reports of Plaintiff's experts permitted by the Court.

Dated: *Feb 21, 2013*



Jonathan E. Greenleaf, M.D.